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Challenges for Economic Analysis under REACH

What can we learn from previous experience?

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Abbreviations

CBA	Cost-benefit Analysis
CEA	Cost-effectiveness Analysis
ECHA	European Chemicals Agency
EINECS	European INventory of Existing Commercial chemical Substances
NGO	Non Government Organisation
OPPT	Office of Pollution Preventing and Toxics
REACH	EU Legislation on Registration, Evaluation, Authorisation and Restriction of CHemicals
RIP	REACH Implementation Project
RRS	Risk Reduction Strategy
SEA	Socio-economic Analysis
SNUR	Significant New Use Rule (US legislation)
TGD	Technical Guidance Document
TSCA	Toxic Substance Control Act (US legislation)
US-EPA	US Environmental Protection Agency
WTP	Willingness to Pay

Executive summary

Background and aim

Socio-economic analysis prior to the regulation of chemicals is a key requirement under REACH, the new European chemicals legislation. Although this is a new development, there is experience from socio-economic assessment in previous chemicals regulation.

In this study, some of the main challenges for performing socio-economic analysis of chemical substances are identified, through assessesment of previous European and US socio-economic analyses. The aim of this assessment is to provide constructive input to the development of guidelines and ultimately improve future socio-economic analysis under REACH.

Methodology

We review 22 EU Risk Reduction strategies and related documents on advantages and drawbacks conducted under the Existing Chemical Substance Regulation 793/93. This is supplemented with a case-based review of six US economic assessments performed under the US Toxic Substance Control Act. Our review does not assess quality of these assessments as such. Also, it should be recognised that direct comparison of the EU and US socio-economic analyses is not possible due to major differences in the respective legislations and the underlying requirements for economic analysis. However, the underlying idea is that similarities or differences in what challenges past EU and US socio-economic analyses face still have the potential to inform development of guidelines for socio-economic analysis under REACH.

Thus, our report identifies a number of areas where socio-economic analysis of chemical substances as previously carried out in practice has potential for improvement relevant for guideline development under REACH.

Identified challenges

The main challenges observed in this report for improving socio-economic analysis in relation to authorisation and restriction of chemical substances are:

- Improved access to useful risk data e.g. through coordination of data and data needs between risk assessments and socio-economic analyses
- Improved access to cost and market data
- Improved methodologies for measuring and expressing benefits in order to ‘translate’ them into monetary form

- More systematic coverage of all relevant options and impacts in detailed quantitative form

- More systematic coverage of uncertainty, assumptions and the ensuing limitations.

Recommendations

The first step in dealing with these challenges will be to ensure that they are explicitly addressed in the guidelines for socio-economic analysis and risk assessment under REACH. Taking proportionality into consideration, it is of course also important that guidelines are realistic and operational. With this in mind, a review of whether the guidelines have been successful in facilitating sufficient quality of analysis would be desirable after a few years of experience. This would also provide input to a revised decision whether minimum standards in certain areas of analysis should be necessary.

Hopefully, the wider use of socio-economic analysis under REACH will in itself lead to improved socio-economic analysis quality, thereby strengthening the decision-making basis for authorisation and restriction of chemical substances. This is a goal worth pursuing. However, it should be clear that this will not simply materialise automatically. Many of the limitations and shortcomings from past experience can be expected to persist under a new system, unless specific action is taken.

Thus, it is not just a question of ensuring that these issues are covered in the guidelines. As demonstrated in this report with regard to uncertainty analysis and coverage of limitations, the development of guidelines on a specific method is no guarantee of its use in practice. It may be necessary to communicate the importance of such analysis even to the extent of making it a requirement that the new European Chemicals Agency (ECHA) would then have to monitor.

What is required is that future socio-economic analyses have a sound logic and well applied methodology that makes the important assumptions and limitations visible for the ECHA. Even with this in place, stakeholders would still be expected to have a wide discretion for how to carry out socio-economic analyses in practice – and there would still be considerable quality verification left for the ECHA. Here, a helpful potential minimum requirement for applications would be for the underlying analyses to undergo obligatory independent quality assessment.

In conclusion

The increased emphasis on socio-economic analysis under REACH has the potential to provide decision makers with a better understanding of the implications of their policy choices. However, even with more resources devoted to analyses, ensuring a balanced, and truly well-informed socio-economic analysis prior to

authorisation and restriction of chemicals under REACH is bound to remain a complicated task.

Resumé (in Danish)

Baggrund og formål

Samfundsøkonomisk analyse i forbindelse med reguleringen af kemikalier er et væsentligt krav under den nye EU kemikalie-lovgivning, REACH. Selvom dette er en ny udvikling, findes der dog erfaringer med samfundsøkonomiske analyser under tidligere kemikalie-lovgivning.

I denne rapport identificerer vi nogle af de væsentligste udfordringer for samfundsøkonomisk analyse af kemikalier gennem analyse af tidligere europæiske og amerikanske samfundsøkonomiske analyser. Formålet med denne rapport er at bidrage konstruktivt til udviklingen af retningslinier og for i sidste ende at forbedre fremtidige samfundsøkonomisk analyser under REACH.

Metode

Vi gennemgår 22 EU Risiko-reduktionsstrategier samt tilhørende dokumenter om fordele og ulemper som er blevet udarbejdet under EU-forordning 793/93 om vurdering af og kontrol med risikoen ved eksisterende stoffer. Dette suppleres med en case-baseret undersøgelse af seks amerikanske økonomiske analyser, som er blevet foretaget under den amerikanske kemikalielovgivning. Vores rapport evaluerer ikke kvaliteten af disse analyser som sådan. Ligeledes skal man være opmærksom på, at en direkte sammenligning af EU og amerikanske samfundsøkonomiske analyser ikke er mulig, da der er store forskelle mellem de pågældende lovgivninger samt de underliggende krav til økonomiske analyser. Den underliggende ide er dog, at ligheder og forskelle i hvilke udfordringer tidligere analyser fra EU og USA har stået overfor, stadig har potentialet til at informere udviklingen af retningslinier for samfundsøkonomisk analyse under REACH.

Vores rapport identificerer dermed en række områder hvor samfundsøkonomisk analyse af kemikalier, som de tidligere er blevet foretaget i praksis, stadig har mulighed for forbedringer, der er relevante for udviklingen af retningslinier under REACH.

Identificerede udfordringer

De største udfordringer, konstateret i denne rapport, med hensyn til forbedret anvendelse af samfundsøkonomisk analyse i forbindelse med godkendelse og restriktion af kemikalier, er:

- Forbedret adgang til brugbare risiko-data, fx gennem af koordinering af data og databehov mellem risikovurderinger og samfundsøkonomiske analyser.
- Forbedret adgang til omkostnings- og markedsdata.
- Forbedrede metoder til at beregne gevinster ved regulering og 'oversætte' dem til monetariseret form.

- Mere systematisk dækning af alle relevante reguleringsmuligheder samt effekter af regulering i detaljeret kvantitativ form.
- Mere systematisk dækning af usikkerhed, antagelser og de tilhørende begrænsninger.

Anbefalinger

Et første skridt til at håndtere disse udfordringer vil være at sikre, at der tages fat på dem i retningslinierne for hhv. samfundsøkonomisk analyse og risikovurdering under REACH. Når proportionalitet tages med i betragtning er det naturligvis også vigtigt at retningslinierne er realistiske og operationelle. Med henblik på dette, ville en revurdering af om retningslinierne har haft succes med at fremme den nødvendige analysekvalitet være hensigtsmæssig efter få års erfaring. Dette ville også bidrage til en revideret beslutning om minimumskrav på særlige analyseområder bør være nødvendige.

Den mere omfattende anvendelse af samfundsøkonomisk analyse under REACH vil forhåbentlig i sig selv føre til en forbedret kvalitet af samfundsøkonomiske analyser, således at beslutningsgrundlaget for godkendelse og restriktion af kemikalier kan blive styrket. Dette mål er værd at forfølge. Det skal dog gøres klart, at dette ikke blot vil ske automatisk. Mange af de begrænsninger og svagheder vi kan observere i tidligere analyser kan forventes at vare ved under et nyt system, medmindre de bliver grebet an med konkrete tiltag.

Det er derfor ikke kun et spørgsmål om at sikre, at disse områder er dækket i retningslinierne. Som vist i denne rapport hvad angår usikkerhedsanalyse og åbenhed omkring analysernes begrænsninger, så er udviklingen af retningslinier på et bestemt område ingen garanti for at de bliver anvendt i praksis. Det kan være nødvendigt at fremhæve betydningen af sådan en analyse – måske ligefrem at gøre det til et krav, som det nye europæiske kemikalie-agentur ECHA derefter skulle kontrollere.

Hovedsagen er at fremtidige samfundsøkonomiske analyser har en solid logik og gennemarbejdede analyser som kan tydeliggøre de vigtigste forudsætninger for ECHA. Selv med sådanne krav vil det stadig kunne forventes at der vil være stort råderum for interessenter til hvordan de vil foretage samfundsøkonomiske analyser i praksis – og der vil stadig være betydelig kvalitetsvurdering tilbage for ECHA. Her kunne et nyttigt potentielt minimumskrav for ansøgninger være at underliggende analyser går igennem en obligatorisk uafhængig kvalitetsvurdering.

Konklusion

Den øgede fokus på samfundsøkonomiske analyser under REACH har potentiale til at give beslutningstagere en bedre forståelse af effekterne af deres beslutninger. Selv hvis der bliver brugt flere ressourcer på samfundsøkonomiske analyser, vil

det imidlertid fortsat være en vanskelig opgave at sikre gennemført balancerede og informerede samfundsøkonomiske analyser i forbindelse med godkendelser og restriktioner af kemikalier under REACH.

1. Introduction

Main points

The purpose of this report is to convey experience from previous European and American socio-economic analyses regarding to authorisation and restriction of chemicals in order to provide constructive input for the development of guidelines for socio-economic analysis under the new European chemicals legislation, REACH.

Socio-economic analysis is becoming a key requirement prior to authorisation or restriction of substances under REACH. This is a new development – though some experience from socio-economic assessment in previous European chemicals regulation does exist.

1.1 Background

The Better Regulation agenda of the European Union is perceived as a cornerstone for the goals laid down in the Lisbon Agenda for stimulating growth and employment (European Commission 2005a). The right balance between costs and benefits of legislation is essential in this context, and the primary tool for obtaining this balance is increased focus on impact assessment of all new policy initiatives arising from the European Commission (European Commission 2005b).

The use of socio-economic methodologies to assess the economic impact of an authorisation or a restriction of specific chemical substances is one of the key instruments in the EU Directive on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) entering into force on June 1. 2007 (European Commission 2006). REACH is a landmark in European chemicals regulation as it shifts the burden of evidence from public institutions (Member States or EU agencies) to the producing or importing companies.

The technical implementation of the previous EU regulation of individual substances is an area that falls outside the domain of the Commission's impact assessment procedures. However, the move towards more elaborate requirements for socio-economic analysis before authorisation and restriction of substances under REACH could be seen as a reflection of the same trends underlying the EU Better Regulation agenda. This is positive. Decisions concerning the regulation of chemical substances should be made on the most well-informed basis possible. Ideally, this should involve quantification of all relevant expected economic effects, including impacts related to health and the environment. A more systematic appraisal of costs and benefits is of value as this assures decision-makers that alternative approaches to reducing identified risks have been considered, that

they better understand the trade-offs of choosing one approach over another, and that their choices include some where benefits to society exceed the costs, and some where they do not.

Prior to REACH it was the responsibility of public institutions to assess the risk posed by substances to human health and the environment, and – if the risks were judged too high – to restrict their overall use. Under REACH it will be the responsibility of importing or producing companies to prove that their chemical products do not pose a risk to human health or the environment. If the substances do pose a serious risk, the importing or producing companies will have to assess the availability of suitable alternatives. If suitable alternatives are unavailable, the companies will have to demonstrate that they can manage the risk, and that the overall economic benefit of producing/using the hazardous substance is higher than the cost to society, including health and environmental externalities. Thus, as presented in Box 1.1, all future restrictions and authorisations with in REACH should be based on socio-economic analyses (SEA). Previously, such decisions were mainly based on risk-based assessments.

Box 1.1
Requirements for socio-economic assessments under REACH

Article 60 Granting of Authorisations

4. […] an Authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all the following elements […] (b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by te applicant or other interested parties […].

Article 68 Introducing new and amending current restrictions

When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure reffered to in Article 133(4) by adopting new restrictions, or amending current restrictions in annex XVII, for the manufacture, use or placing on the market of substances on their own, in preperations or in articles, pursuant to the procedure set out in Articles 69-73. Any such decision shall take into account the socio-economic impacts of the restriction, including the availability of alternatives. (European Commission 2006).

The framework of REACH opens the way for a broad application of SEA tools by all interested parties. To gain a fuller view of costs and benefits of proposals for regulation of specific substances, the EU is establishing the European CHemicals Agency (ECHA) and a Socio-Economic Analysis Committee to which all stakeholders may submit SEAs or other data in order to support their preferred options (European Commission 2006). SEA has been included as a central tool in REACH in order to encourage and ensure that substances of high concern are eventually replaced by less dangerous equivalents or by technologies where suitable economically and technically feasible alternatives are available.

Previously, there were only limited requirements for performing SEA in EU chemicals legislation. The previous EU regulation that led to the most extensive utilisation of SEA with regard to chemical substances was the Existing Substance Regulation No. 793/93/EEC.[1] This regulation required Member State Rapporteurs to assess risks and recommend risk reduction strategies for existing substances on the EU priority lists. Most Risk Reduction Strategies (RRSs) were conducted according to the Technical Guidance Document on Development of Risk Reduction Strategies (TGD), which promotes analyses of economic impact of suggested risk reduction strategies and alternative substances and technologies. These RRSs may therefore serve as good indicators of how SEA has been used to assess the impact of previous regulation of chemical substances in Europe. In the instances where marketing and use restrictions have been proposed as the outcome of the RRSs, additional analysis of advantages and drawbacks according to the TGD on Development of Risk Reduction Strategies have been performed. Where such assessments have been provided in additional reports and where they could be obtained, we have included them in our sample.

The requirements for conducting SEA in the TGD on Development of Risk Reduction Strategies were not absolute, and left a wide discretion for the performance of SEA in practice. For example, SEA could range from rough qualitative estimates to detailed economic analyses of advantages and drawbacks (European Commission, 1998). Thus, a priori the use of SEA in these RRSs would be expected to be neither common, nor well-developed.

REACH implies higher ambition with regard to the use of SEA in practice. This has motivated the present analysis of the main constraints for performing SEA under the previous EU legislation. This should help provide information on how an expanded use of SEA can contribute to an improved decision-making basis under REACH.

[1] Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.

Outside the EU, the US probably has the most prolonged experience with use of SEA in connection with authorisation and restriction of chemicals. The use of SEA to regulate industrial substances has been an integrated part of the US Toxic Substance Control Act (TSCA) since it was passed in 1976. TSCA directs the US Environmental Protection Agency (US-EPA) to use the least burdensome option to reduce risks to a reasonable level compared with the benefits provided by the product – using SEA methodologies for the evaluation (Tickner et al. 2005). In order to present an alternative perspective and other possible paths and options for using SEA in connection with authorisation and restriction of substances under REACH, our report also contains a case-based analysis performed on a small sample of different types of economic analyses undertaken by US-EPA. Given the higher formal requirements for conducting SEA in US-legislation compared to in the TGD on Development of Risk Reduction Strategies in the EU, the use of SEA by US-EPA would be expected to be more elaborate than under previous EU legislation. Thus, it would be interesting to evaluate the current practice of SEA under US chemicals regulation – to assess what constitutes good practice and what are constraints for performing SEA in the US. Together with the experience from previous EU legislation, this is used to provide recommendations as to which areas of concern to include in the guidelines for SEA under REACH.

The procedures for SEA under REACH are being considered by the European Commission and being developed under the REACH Implementation Project 3.9 (Postle et al. 2006). Our report aims to inform this process – specifically the work going on in RIP 3.9 – by highlighting some lessons to be learned from previous European and US experiences with SEA in connection with authorisation and restriction of chemical substances.

2. Objective, methods and scope

Main points

This report aims to identify constraints associated with applying socio-economic analysis in relation to regulation of chemicals, based on previous experience. This is done in order to identify key areas where such analysis could be further developed.

This report reviews the content of 22 EU Risk Reduction Strategies conducted under the Existing Chemical Substance Regulation 793/93. The report employs a checklist on the Risk Reduction Strategies, focused on number of risk reduction measures considered, types of impacts analysed, degree of quantification/monetisation, methods used in monetisation, and treatment of limitations and uncertainties.

Furthermore, the report assesses how the same issues have been dealt with in six economic assessments undertaken by the US Environmental Protection Agency.

2.1 Purpose of report

The purpose of this report is to provide useful and constructive input for the development of guidelines for socio-economic analysis (SEA) relating to authorisation and restriction of substances under REACH.

We seek to achieve this purpose by

- Presenting an overview of how socio-economic and other economic analyses have been applied under recent EU and US chemicals legislations
- Identifying main constraints with the aim of improving the use of such socio-economic analysis under REACH.

2.2 Methodology

This report reviews a sample of 22 Risk Reduction Strategies (RRS) and related documents on advantages and drawbacks conducted under the Existing Chemical Substance Regulation 793/93/EEC. Our assessment of these EU reports is conducted through the use of a systematic checklist (see Appendix 4) focusing on: the alternative policy options assessed, which and how impacts have been analysed; the level of detail of analyses in regard to degree of quantification; the methodological approach used; data availability; and treatment of uncertainty and limitations.

This report also reviews a sample of six US economic assessments with focus on the same issues as for the EU analysis, but given the small sample, this assessment is case-study based – see section 2.3.2.

Our overall perspective is 'welfare economic' – i.e. in principle it takes all cost and benefits to European citizens into account, including social and environmental effects. We use this as the theoretical best practice standard of economic analysis. In this respect, this report corresponds to Postle et al. (2006), which presents state of the art of economic analysis of chemicals regulation. One difference between the current report and Postle et al. (2006) is our emphasis on overall costs and benefits as the main perspective. This does not mean that cost-benefit analysis in the formal sense is our benchmark, but that a cost-benefit 'perspective' should be taken. In this perspective, other possible methods, e.g. multi-criteria analysis and cost-effectiveness analysis should be seen as fundamentally being second-best.[2]

In our analysis of European and US risk reduction strategies we have used this high academic standard as our reference benchmark. This should not be seen as an indication that this is necessarily the standard that these reports should attain. In practice, such analysis may be quite difficult due to considerations concerning the appropriate proportionality of analysis and availability of data. While maintaining this admittedly ambitious benchmark throughout our assessment, the more practical and realistic aspects will be discussed as well – see section 2.2.1 and particularly the discussion in chapter 5.

The purpose of this is to make it transparent to what extent current practice is different from the academic benchmark – not necessarily as a criticism of current practice, but in order to increase awareness of barriers to improvement of future economic analysis in this area.

As for the EU, the RRSs assessed in this report are those that have led to European Commission recommendations in the EC Official Journal prior to June 2006. When the proposed risk reduction measure was a restriction on use and marketing of the substance, some Rapporteurs included an analysis of Assessment of Advantages and Drawbacks in the RRS and others conducted separate reports of advantages and drawbacks. We have strived to include and obtain both the RRS and the separate report on Advantages and Drawbacks when present. In total, 27 Risk Reduc-

[2] Under the Existing Chemical Substance Regulation 793/93 a focus on cost-effectiveness analysis have been warranted in some cases, since the goal of Risk Reduction Strategies could be to identify ways of achieving a given acceptable level of risk. Under REACH, the basic approach would rather be to balance the risk level against what overall costs and benefits a policy option entails.

tion Strategies and related documents were obtained from the responsible Rapporteurs, including updates of earlier Risk Reduction Strategies. Only one of the RRSs fulfilling our selection criteria was not readily obtainable. When multiple reports were obtained for the same substance these were merged and treated as one.[3] Reducing the total sample size to 22, Appendix 1 includes a detailed list of the Risk Reduction Strategies covered.

A special case occurred in the coverage of the substances 2-propenoic acid (79-10-7) and methyl methacrylate (79-41-4), which the Rapporteurs have assessed together in two different reports focusing on limiting risk for either the environment or for human health in relation to workers. These reports have been treated as two separate reports.

2.2.1 Proportionality considerations

A central question regarding SEA as carried out in practice is what level of detail is required in order to enable sufficiently informed decision making. The level of detail of the analysis has several dimensions: the number of risk reduction measures covered; the number of impacts of each measure covered; and the level of detail (e.g. quantification) at which each of these impacts is covered.

An ideal SEA should focus on overall social costs and benefits to society. Thus, a SEA based on data that focuses mainly on short-term economic costs and/or limited treatment of environmental and social impacts presents only a portion of the overall picture. On the other hand it should be recognised that lack of appropriate data or other difficulties may hinder the realisation of an 'ideal' analysis. However, this should not warrant a misplaced focus on options or impacts, where data are available, if these are not important. Indeed this would constitute a non-proportional analysis.

Proportionality considerations relate to indications of when detailed and resource demanding quantitative analyses are necessary, and when less ambitious exercises are justified. In the context of regulatory legislation, this question relates to the level of quantification, the number of policy options or alternative substances,

[3] In three cases two Risk Reduction Strategies have been paired and treated as one in our analysis. This applies to the following: 1) The Risk Reduction strategy on O-Anisidine (90-04-0) from 2002 is an update of the Azo-dyes report from 1997; 2) The Regulatory Impact Assessment of Pentabromodiphenyl Ether (32534-81-9), and the Risk Reduction Strategy and Analysis of Advantages and Drawbacks of the same substance from 2000; and 3) The Risk Reduction Strategy on Nonyphenol (25154-52-3) from 2000, and the Regulatory Impact Assessment on the same substance from 2002, and treated as one RRS.

and technologies included in the analysis, and the emphasis on economic vs. social, health and environmental impacts (Nielsen et al. 2006).[4]

For SEAs carried out by applicants for an authorisation, the framework of the REACH application system partly reduces the question of proportionality from a central to a decentralised decision by the individual applicant. Postle et al. (2006) argue that even if it is not mandatory to include a SEA in the dossier for a chemicals evaluation, the applicant will face incentives to include a socio-economic assessment to ensure that the dossier provides a good basis for decision making. A well-informed decision on chemicals regulation requires a SEA, but the level of detail needed within the SEA may vary from case to case. The applicant will implicitly decide on a level of proportionality and hence the detail level of the data analysis to submit to the European Chemicals Agency. However, the applicant will do so in full competition with third party interest groups, who will also make similar implicit decisions on the level of detail of their analysis. Eventually, the ECHA should judge whether the analyses undertaken by applicants are sufficient or not. At the same time, explicit consideration of proportionality in the guidelines for SEA under REACH could potentially guide applicants towards what would be generally acceptable levels of detail in the analyses.

For SEAs carried out by Member States as part of a restriction procedure, the level of proportionality could also be a decentralised decision, but need not necessarily be so. We will return to this issue when discussing possible ways of ensuring proportionality in chapter 5.

2.3 Report scope

It is important to recognise that SEAs undertaken under EU regulation 793/93/EEC and the US TSCA should not be directly compared. The respective legislations are not similar, and neither are the SEA guidelines. Furthermore, we have applied different criteria for sample selection for the two legislations.

2.3.1 Scope of reviewing socio-economic assessment in EU reports

While this report focuses on the use of SEA under recent EU chemicals legislation, it should be emphasised that we are solely looking at SEAs undertaken under regulation 793/93/EEC. Some SEAs may have been conducted under other legisla-

[4] In principle, social and environmental impacts should be included in a truly economic analysis. In much EU Commission literature, e.g. the EU guidelines for Impact Assessment (European Commission 2005a), a distinction between economic, social and environmental impacts is made – i.e. providing a more narrow interpretation of the term economic. In order to facilitate a comparison with EU literature, we employ this distinction between impact categories in this report.

tions – e.g. the Marketing and Use Restrictions Directive 76/769.[5] Extensive socio-economic assessments focused on the overall benefits and costs of REACH have been performed by authorities and interested parties in connection with the preparation of the REACH legislation. Since we focus on the socio-economic analysis of regulation of *single* chemical substances, these types of analyses have not been covered in this report.

As mentioned in the introduction, the Risk Reduction Strategies have been conducted according to the TGD on Development of Risk Reduction Strategies (European Commission 1998). The TGD on Development of Risk Reduction Strategies contains different requirements for analytical standards depending on what risk reduction measures have been proposed. Accordingly, the scope of SEA tools used in RRSs accordingly depends on whether a restriction on marketing or use is suggested as a risk reduction measure. In the analysed material, some RRSs only concern different policy options and/or the use of alternative substances or technologies, using mainly qualitative analysis. Other RRSs include quantitative analyses of the effects of a few promoted options. This difference in RRS setup presents a limitation on how much can be deduced from our results with regard to the number of alternative options covered.

The substances covered in the RRSs have been chosen by the member states on the basis of the information collected in relation to Regulation 793/93/EEC, and prioritised with respect to risk for man or environment. The framework for choosing the most important toxic chemical substances could therefore be assumed to be robust, but as exemplified by the inclusion of the chemical substance acrylamide[6], substances may also have been included due to political interest after hazardous incidents.

The assessments sampled in this report analyse the 22 substances on priority lists 1, 2 and 3, on which the Commission reached a political decision before June 2006. This may reflect the toxicity of the substances concerned, the ranking on the priority list, the sequence of submission, the time used on negotiating with the industry, or that these reports are the only ones that fulfil the general requirements. It is not certain therefore whether these substances are the most appropriate to handle first, or whether substances not included here pose a greater risk, but face a more demanding regulatory process. This also limits our results as very

[5] However, as mentioned earlier, we do include analyses of advantages and drawbacks in the instances where the RRSs have lead to marketing and use restrictions, and where such analyses were obtainable.

[6] Acrylamide functions as a chemical grout in sewer, manhole and pipeline repairs. After two instances of inappropriate handling (in Sweden and Norway) leading to contamination of workers, acrylamide attracted political focus that led to a totally national ban in Sweden and Norway and eventually to the inclusion of this substance in the EU priority list (Fenn 2000),

comprehensive SEA may have been conducted in those RRSs which did not lead to a political decision by the European Commission.

The RRSs covered by this report were obtained from the responsible Member States or directly from the consultants who produced the reports. The reports were obtained trough websites or by written requests.

Three authors have applied the checklist to three arbitrarily chosen RRSs in order to compare results and ensure consistency in checklist completion. The remaining RRSs were subsequently read and categorised by one author.

The present review of the application of SEA in European chemicals legislation generally follows the framework presented in Nielsen et al. (2006). For the sake of reproducibility a systematic checklist has been applied to cover a number of methodological issues, which as far as possible are defined objectively. In those cases where impacts were assessed in qualitative terms it was necessary to further distinguish between briefly mentioned and more comprehensively discussed impacts (see Box 2.1). In contrast to the other questions in the checklist, this has required some subjective evaluation on our part.

The degree to which the Rapporteurs have presented and analysed the impacts, based on the proposed risk reduction strategy, determines the strength and applicability of the recommendation. Box 2.1 presents the four different degrees of analysis of impacts applied in this report; here, level of detail of coverage for each type of impact analysed increases from 'Briefly Mentioned' to 'Monetisation'. From a strictly socio-economic perspective, impacts should preferably be presented in monetary terms. This would make it possible to feed data into a Cost-Benefit Analysis (CBA) that would generate benefit figures comparable to the predicted cost of the RRS. Where such monetary figures of benefit are too difficult or costly to obtain, a SEA expressed in terms of a Cost-effectiveness Analysis (CEA) could still be produced as long as quantitative measures for dose-response functions are available, i.e. the relationship between exposure to the substance and impact on e.g. health status. A SEA becomes difficult to interpret when the majority of impacts are only qualitatively described, and almost impossible when only briefly mentioned impacts are available.

Notwithstanding the overall desirability of quantified and monetised impacts, we acknowledge that the assessment of SEA in regard to risk reduction strategies is complex and that it may be out of proportion to assess impacts in all areas. Thus, the inclusion of non-essential impacts in briefly mentioned form is acceptable.

Box 2.1
Degrees of quantification

In our analysis we distinguish between the following four degrees of impact analysis:

Briefly mentioned (BM): the Rapporteur generally states that a specific impact may or may not occur. There is no assessment of the probability or the size of the impact in either qualitative or quantitative methods.

Qualitative (Ql): impacts are described in detail in relation to the main areas of impact, but no quantitative estimates are given.

Quantified (Qn): impacts are quantified, e.g. in terms of reduced number of workers exposed, or magnitude of emission.

Monetised (M): impacts are quantified in monetary form, particularly but not exclusively with respect to benefits to man and the environment.

Where RRSs have referred to background documents for further detail, we have generally not consulted these references. Instead, our analyses have been performed on the impacts summarised in the RRSs themselves. This has the drawback that more elaborate coverage of e.g. health and environmental impacts in underlying Risk Assessments Reports may not come through fully in our checklist.

The checklist we have used was developed in order to assess various topics in relation to socio-economic assessments of substances. As previously mentioned this includes choice of methodology, data availability, the number of options considered, the type of socio-economic methodology, and the degree of monetisation and other types of quantification.

This report focuses on the degree to which SEA has been conducted and thus constitutes what Harrington & Morgenstern (2004) term a 'content test' of an assessment system - i.e. a review of what is included in the analysis. We refrain therefore from analysing the degree to which the reports have succeeded in describing the *main* impacts relevant to a given context, nor do we try to assess the quality of the quantification as such. This also means that our focus on quantification should not be seen as an indicator of quality as such.[7]

Using the methods of Nielsen et al. (2006), the results are mainly presented in the form of descriptive statistics, cross-tabulating different criteria with basic characteristics of the analyses. In this way it is possible to establish correlations between

[7] Numerous analyses published in the run-up to the final REACH vote would score high on a quantification scale but could still be seen to be of overall poor quality (Pelkmans 2005).

main variables, but not to establish causal effects of the patterns of quantification observed. Similarly, due to the limited sample size and many variables, multivariate regression analysis is not performed. Hence the results cannot be statistically tested for influence of other variables. However, the possible interpretations and the limitations of the results will be discussed throughout the report.

2.3.2 Scope of reviewing economic assessment in US reports

In this report, the analysis of economic assessment of substances in the US takes its point of departure in the results from Chapter 3 concerning the European experience. The approach is to compare the observations from Chapter 3 with the observations from the six US-EPA reports used as cases.

To view the application of SEA under the US chemicals regulation we have chosen to examine six reports undertaken in three different contexts that reflect the array of application of economic assessments currently performed by the US-EPA. Of these reports, two contain a fairly comprehensive analysis of overall costs and benefits, two cover the cost of enforcing an application rule, and the last two present market assessments conducted to obtain a more in-depth understanding of the substances market before pursuing risk management options. The six reports in our sample were obtained through correspondence with US-EPA.

While we present the results of our analysis of SEA in EU RRSs (chapter 3) as quantitative descriptive statistics, we use a more qualitative approach in our analysis of economic assessments in US reports (chapter 4). This is the result of having a small-size sample and a sample selection that does not ensure that the analyses covered are fully representative. As in our study of EU SEAs, the main focus in our study of US cases is also choice of methodology, data availability, the number of options considered, the type of socio-economic methodology, and the degree of monetisation and other types of quantification.

It should be emphasised that we do not include any analyses undertaken under the TSCA Title I, Section 6, under which the most elaborate examples of analyses of costs and benefits of regulation of chemical substances have been undertaken in the US. We have chosen not to include any such studies in our sample, since no analyses have been carried out in the recent past under this section. Our US sample should therefore more be seen as an example of current practice than as an example of best practice.

3. The EU experience with socio-economic assessment of existing chemicals

Main Points

Our analysis of socio-economic assessment in 22 Risk Reduction Strategies (RRSs) performed under previous EU chemicals regulation shows that:

- The RRSs generally included a high number of options
- The main part of the RRSs focused on assessing negative impacts rather than positive health and environmental impacts
- Approximately half the RRSs conducted monetised assessments
- Approximately one third of these monetised analyses estimated the benefits of the promoted risk reduction measures
- Rapporteurs do not generally reflect on what implications the choice of methods and the availability of data have for certainty of results and overall limitations of the report
- RRSs that include quantitative assessments are also those that reflect the most on the uncertainty and limitations of their results.

This chapter examines the use of socio-economic assessment (SEA) methodologies in 22 Risk Reduction Strategies. The background for the analysis is presented – i.e. a short description of EU chemicals legislation prior to and under REACH in regard to the role of socio-economic analysis (section 3.1). This is followed by our main results and discussions in relation to: clarity of objectives and conclusions and coverage of options (section 3.2); coverage of impacts and use of economic methodology (section 3.3); the inclusion or exclusion of uncertainty and sensitivity analysis (section 3.4); coverage of limitations of analyses (section 3.5); and the importance of who performs RRSs (section 3.6).

3.1 EU chemicals legislation before and after REACH

3.1.1 Chemicals regulation in EU before REACH

Before REACH, the valid chemicals regulation for restricting marketing and use of substances in force was the Existing Substance Regulation 793/93/EEC, which covers approximately 100000 chemical substances listed in the EINECS (European Inventory of Existing Commercial chemical Substances).

Under this legislation, it was mandatory to assess the socio-economic impacts of a substance and the availability of substitute substances if a restriction on marketing and use of the substance was proposed (Regulation 793/93/EEC article 10.3). This regulation introduced a comprehensive framework for the evaluation and control of 'existing' chemical substances. The procedure is briefly presented in Box 3.1.

The practical approach to socio-economic methodologies is covered by the TGD on Development of Risk Reduction Strategies, which is not legally binding but represents a common commitment by the Commission, Member States, and NGOs on how to frame risk reduction strategies. The TGD on Development of Risk Reduction Strategies outlines possible risk reduction measures (see Box 3.2), implementation instruments and criteria for selecting the most appropriate approach, but only as minimum requirements.

3.1.2 Chemicals regulation under REACH

On December 13 2006, the REACH Directive was passed in the EU parliament. REACH requires substances to be registered and evaluated by the new established European CHemicals Agency (ECHA). Thus manufacturers and importers must obtain and submit all relevant information (as specified by Annex XV in the REACH Directive) on uses and characteristics of their substances. Substances having properties of very high concern will then be subject to authorisation, i.e. the applicants will have to demonstrate that risks associated with the use of these substances are adequately controlled. Furthermore, an authorisation may be granted for use of a given substance, whose benefits are shown by a socio-economic analysis to outweigh the costs and when there are no suitable alternatives. Additionally, a Member State or the European Chemical Agency may propose restrictions on use and marketing of a substance in order to manage Community-wide risks that are otherwise not adequately controlled.

Box 3.1
Risk Reduction Procedure under the EU Directive 793/93/EEC.

The EU Regulation 793/93/EEC requires the evaluation and control of risk posed by existing substances to be carried out in four steps:

Step 1 Data collection: companies manufacturing or importing chemical substances in amounts exceeding 10 tonnes per year are required to submit information on these substances every three years.

Step 2 Priority setting: based on this information the European Community, in consultation with the Member States, will draw up a priority list of substances. Four such priority lists were published subsequent to 1994.

Step 3 Risk assessment: substances on the priority list are subject to an in-depth risk assessment of impacts posed to man and the environment. This risk assessment is prepared by Member States acting as Rapporteurs based on the framework set out in Directive 1488/94/EC and the Technical Guidance Document on Risk Assessment for New and Existing Substances. The first draft of the risk assessment reports are written by the Rapporteur and final drafts are conducted through consensus with interested parties.

Step 4 Risk reduction: if the risk Assessment concludes that the substance is of high concern and not adequately controlled, a Risk Reduction Strategy (RRS) must be conducted by the Rapporteur and submitted to the EC. The Rapporteurs are recommended but not required to conduct their RRS within the framework of the Technical Guidance Document on Development of Risk Reduction Strategies and the scope of the report is decided by the responsible Member State.

Box 3.2
Risk reduction measures

Risk reduction measures are the tools that are available under EU or Member State legislation for reducing the risk posed by the substance. These measures can range from requirements for labels or safety sheets concerning products, protective equipment for workers, and standards for emission levels to voluntary agreement with industries or an outright ban on the substance.

Article 64(4)(b) of the REACH Directive specifies the use of socio-economic analysis in connection with a proposed restriction, and Article 60 (4) (a-d) outlines the criteria for granting authorisations for substances of very high concern (European Commission 2003). The Annex XVI of the Directive specifies that the same type of socio-economic analysis is required both for granting authorisation and proposing restrictions (see Box 3.3).

Box 3.3
The socio-economic requirements in the Annex XVI of the REACH Directive

The requirements for the socio-economic analysis that are submitted to the European Chemicals Agency are presented in the Annex XVI of the REACH Directive.

This information includes: consideration of the impact on industries, impact on other players in the supply chain, downstream users, and associated businesses in terms of investment and operating costs; impact on consumers, social implications, the availability, suitability, and technical feasibility of alternatives; wider implications on trade and competition; alternative risk management; and social and economic benefits.

To ensure efficient implementation of REACH, the European Chemicals Bureau (ECB) is currently undertaking a number of REACH Implementation Projects (RIP). In RIP 3.9, a SEA guidance document are being developed (Postle et al. 2006). It is important to note that the purpose of RIP 3.9 is to review and evaluate best practices for impact assessments in chemicals regulation. RIP 3.9 should therefore be seen as a source of ideas more than as a general guide. The SEA recommendations discussed under RIP 3.9 that are important for this report, are briefly presented in Box 3.4.

Box 3.4
Recommendations for socio-economic assessment in RIP 3.9 (Postle et al. 2006)

Impacts of a granted or refused authorisation on *the applicant(s)*, or in the case of a proposed restriction, the impact *on the industry* (e.g. manufacturers and importers). The impacts on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impacts on investments, one-off and operating costs.

Impacts of granted or refused authorisation, or a proposed restriction, *on consumers;* for example, on product prices, changes in composition, the quality or performance of products, availability of products, and consumer choice.

Social implications of granted or refused authorisation, or a proposed restriction; for example, job security and employment.

Availability, suitability, and technical feasibility of *alternatives,* and economic consequences thereof, and information on the rates of, and potential for technological change in the sector(s) concerned. In the case of an application for authorisation, this may include social and/or economic impacts of using any available alternatives [...].

Wider *implications on trade, competition and economic development* (in particular small- and medium-sized enterprises (SMEs) of granted or refused authorisation, or a proposed restriction. This may include considerations of local, regional, national or international aspects.

In the case of a proposed restriction, proposals for *other regulatory or non-regulatory measures* that could meet the aim of the proposed restriction (this must take account of existing legislation). This should include an assessment of the cost linked to alternative management measures.

In the case of proposed restriction, the *social and economic benefits* of the proposed restriction; for example worker health, environmental performance and the distribution of these benefits, i.e. geographically or population groups.

3.2 Objectives and coverage of options in Risk Reduction Strategies

This section deals with the degree to which the stated objectives and the conclusions in the RRSs included in our sample are clear. This is followed by our results with respect to coverage of risk reduction options, including substitutes.

3.2.1 Objectives and conclusions in EU Risk Reduction Strategies

Table 3.1 presents the distribution of reports according to whether they have clear, unclear or no objectives formulated in the RRSs. Two thirds included an objective, although in many instances this was not very clear. Approximately one third of RRSs did not include an objective at all; this could be explained by the fact that the Rapporteurs prepared the RRSs according to the investigative procedure in Regulation 793/93/ECC (see Box 3.1), and therefore may not have found it necessary to clearly state an objective, as this was stated in previous documents. However, even though the main focus of the RRSs is by definition to present risk reduction strategies, the presence of a clearly formulated objective in the RRSs should be expected.

Table 3.1
Types of objectives in the Risk Reduction Strategies

	Clear objective	Unclear objective	No objectives
Type of objective	9	6	7

Note: N=22

In order to provide the policy makers with a good tool for decision-making it is important that RRSs based on SEA clearly present the conclusions of their studies. The conclusion should provide information on proposed risk reduction measures and the certainty or limitations on which this conclusion is based. Considerations on uncertainties are necessary in order to make the recommendations and their background transparent to policy makers. We will return to the issue of uncertainty and limitations in sections 3.4 and 3.5.

As shown in Table 3.2, 14 RRSs contained clear conclusions as required by the TGD on Development of Risk Reduction Strategies, while eight had unclear or no conclusions. Table 3.2 shows that a relatively large proportion of the RRSs with a clear conclusion also showed a clear relationship to the objectives, and provided clear information on the choice of risk reduction measure. These aspects did not occur to the same extent in the reports with unclear conclusions.

Table 3.2
Summary of conclusions in the Risk Reduction Strategies

	Clear conclusion	Unclear conclusion	Total
Number of reports	14	8	22
Clear recommendation of policy option(s)	13	8	20
Clear information on choice of option	9	2	11
Clear relationship to the objective	11	1	12

Note: N=22

3.2.2 Number of risk reduction measures covered

In order to make informed policy decisions it is essential for policymakers to be equipped with the best possible information on different options before decisions are taken. Thus, both the TGD on Development of Risk Reduction Strategies and REACH promote assessment of several risk reduction measures in order to prevent policymakers from prematurely disregarding relevant measures and thereby make inexpedient conclusions. To seek an informed solution it is important that the risk reduction measures considered are representative of the whole range of available alternatives (Postle et al. 2006). RRS based on TGD on Development of Risk Reduction Strategies are required to consider several risk reduction measures, and to choose the measure or combination of measures that is most expedient. This is obtained in practice in TGD on Development of Risk Reduction Strategies by suggesting a stepwise approach to risk reduction measures as presented in Box 3.5.

Box 3.5
The TGD on Development of Risk Reduction Strategies approach to assessing risk reduction measures (European Commision 1998)

Step one: presently applied risk reductions measures
TGD on Development of Risk Reduction Strategies based reports normally present those risk reduction measures that at the time of the analysis are legally applied to control the risks from the chemical substance in question. This includes a brief discussion of the possibility of further reducing the risk within the framework of these risk reduction measures.

Step two: screening of effective risk reduction measures
Preliminary assessment of the available risk reduction measures that might reduce the risk posed by the substance. The most suitable measures are then selected and analysed, e.g. in relation to effectiveness and cost.

Step three: conclusion proposing risk reduction measures
Based on the analyses in the RRS one or more risk reduction measure(s) are then proposed in the conclusion.

In the following assessment of risk reduction measure coverage in the RRSs, each step presented in Box 3.5 is categorised accordingly: 'Existing Measures' refers to step one; 'Analysed Measures' refers to step two, and 'Proposed Measures' refers to step three. The results of measures presented in Table 3.3 are based on a categorisation of different measures that can be seen in Appendix 3.

Using the categories in Appendix 3 the results are summarised in Table 3.3, which shows that on average the RRSs cover 3.3 categories under the heading of Existing Measures, 4.2 under Analysed Measures, and 2.2 under Proposed Measures. This

covers a range of 0 to 5 for Existing Measures, 2 to 8 for Analysed Measures, and 0 to 5 for Proposed Measures.

Compared with the maximum of nine possible types of measure categories, 4.2 as the average number of Analysed Measures seems relatively high. However, it is not possible to determine through our analysis whether all relevant measures have in fact been covered.

Table 3.3
Average number of all measure categories present in Risk Reduction Strategies

Measures	Existing	Analysed *	Proposed
Total	73	93 (109)	49
Average	3.3	4.2 (5.0)	2.2
Min	0	2 (2)	0
Max	5	8 (9)	5

Note: N=22
* Numbers in brackets indicate the total number of Analysed Measures (i.e. including Existing Measures). See Appendix 3.

The number of risk reduction measures covered in the RRS under each category and for each step is presented in Table 3.4. This shows that out of 22 RRSs, 16 assess the impacts of restricting marketing or use of the substance and 10 recommend this measure. One half to two thirds of the RRSs analysed the impacts of setting new emission level standards, improving the information on the end-products, or improving worker safety, but only for two fifths of the RRSs were these measures recommended. Furthermore, in 19 RRSs the substances have been subject to national restrictions prior to the EU legislative process, but only in two RRSs are future national policies recommended as risk reduction measures.

Table 3.4
Number of Risk Reduction Strategies covering different risk reduction measures

	Existing	Analysed	Proposed
Restriction on marketing	3	16	10
Product safety	2	7	1
Reduction of emission levels	12	16	9
Improved information	15	13	9
Improved worker safety	16	14	9
Voluntary programmes	6	5	1
Alternative substitution	0	15	7
National Policies	19	0	2

Note: N=22

Nearly three fifths of the 22 RRSs analyse the impacts of substituting the substance by technical or chemical means, but in only seven RRSs was this a recommended risk reduction measure.

3.2.3 Coverage of substitutes

In order to present the correct risk reduction measures, the Rapporteurs were obliged to analyse the availability of alternatives, including alternative substances, processes and/or products, which fulfil the same function. Any alternative must be assessed in terms of the degree to which substitution can occur in areas such as:

- Technical feasibility (ability of the alternative to meet the function of the substance concerned) (Postle et al. 2006).
- The effects on health and environment (the potential of the alternative for reducing risk and the degree to which it may give rise to other indirect impacts)
- The economic impact (the viability of alternatives in terms of known relative costs, the applicability of the alternative to the entire sector and the changes the alternative will bring to the processing sectors), including social impacts.

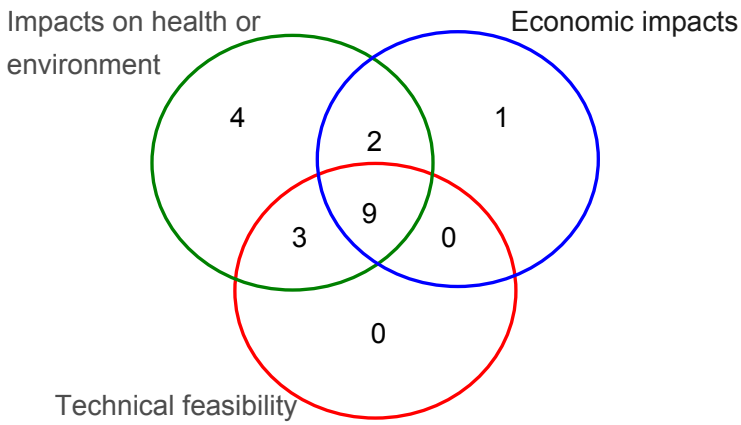
Table 3.5 presents the degree to which quantification is utilised for analysing impacts of alternatives. Our study shows, that of 22 RRSs 19 analysed substitutes, with 15 conducting qualitative or quantitative analysis of substitutes, but only 11 using quantitative methods. It is striking that monetary quantification was only performed on the economic effects. Out of 11 assessments of economic impacts, only six reports used analytical methods involving monetisation. However, the lack of monetised assessment of technical feasibility and effects on health and environment should be seen in the light of the small scale analysis to which alternatives were subject in most RRSs. Calculating estimates of these aspects in monetary terms is particularly difficult and resource-intensive.

Table 3.5
Assessment of subtitution as a risk reduction measure

	Briefly Mentioned	Qualitative	Quantitative	Monetised	Total (excl. BM)
Technical feasibility	2	8	2	0	10
Effects on health or environment	5	11	2	0	13
Economic impact	1	4	1	6	11

Note: N=22
* A total of 19 RRSs have assessed alternatives, of which four only briefly mentioned the effects

The distribution of RRSs that assess the different areas in regard to substitution is presented in Figure 3.1. This shows that nine of the 19 RRSs that considered substitutions assessed all three areas. 18 RRSs considered the effects of on health or environment, with four assessing the area exclusively and three also considering technical feasibility. The single RRS that does not include considerations of effects on health and environment only assessed economic impacts.



N=19

Figure 3.1 Risk Reduction Strategies with different combinations of impact assessment on health or environment, economic impacts, and technical feasibility.

3.3 Coverage of impacts and economic methodology

3.3.1 Use of baseline scenarios

A baseline scenario can be relevant as a benchmark to compare what the economic and risk implications of a measure will be compared to a business-as-usual situation. As the overall strategies of the RRS were to reduce the risk of substances presented in previously conducted Risk Assessment reports, data from these reports and in some cases additional data from the industry concerned were used as baselines in most RRSs. Likewise, the main part of the RRSs assess whether present risk management strategies can be used to fulfil the requirements of the risk assessment. Hence, this is often used as a general baseline. However, we have not systematically analysed this aspect further in this report. It should be noted that the TGD on Development of Risk Reduction Strategies suggests that alternative risk reduction measures may be analysed as the baseline, as the current situation is usually not a real decision alternative, but that the formal regulation requirement is merely that advantages and drawbacks are analysed in relation to the proposed restriction (European Commission 1998).

3.3.2 Balance between coverage of environmental, economic and social impacts

According to the TGD on Development of Risk Reduction Strategies, impact criteria should only cover those triggering the actual risk, and impacts may be described qualitatively or quantitatively, and should include: risk of substance and substitute(s) to human health or environment, costs and benefits to the producer(s) of the substance and substitutes, costs and benefits to the users or other stake-

holders, and other factors, such as administrative burden, employment etc. (European Commission 1998) p 36.

Within the checklist applied to the 22 RRSs covered by this report, the range of impacts is grouped into the following three areas: Environmental impacts, Economic impacts, and social impacts. The checklist covered the three areas in terms of 37 subcategories of which 24 appeared in the RRSs.[8] Each subcategory was assessed with regard to degree of quantification of impacts. The coverage of impacts in different areas in the 22 RRS in our sample were:

- 21 RRSs included economic impacts e.g. transitional, capital and operating cost, competitiveness, cost of innovation and research.
- Six RSSs included social impacts within five categories e.g. employment, possible accidents, and private sphere.
- Five RRSs included environmental impacts within seven categories including e.g. waste, greenhouse gas emission, and particle emission.

In the 22 RRSs a total of 102 impacts have been covered with an average of 4.6 types of impact per RRS. The number of types of impact assessed in each report ranged from zero to nine. Based on the 24 possible types of impact, 4.6 may appear as a relatively low number, but it is outside the scope of this analysis to assess whether or not all relevant types of impacts have been covered by each RRS.

The SEA requirements to assess social and environmental impacts when appropriate and not only to focus on economic impacts have in general not been fulfilled in the RRSs in our sample. The number of impacts analysed within each type of impact in the different RRSs are presented in Table 3.6. For the social and environmental impacts the number of impacts is in general very low, with an average of 0.2 and 0.4 impacts per assessment. Furthermore, Table 3.6 shows that a relatively large proportion of impacts have only been considered briefly, and have not been directly analysed with regard to their impact. The inclusion of impacts covered in a briefly mentioned (BM) form can be very context related. It should be mentioned that in several RRSs, where a comprehensive quantitative assessment of impacts were conducted, the Rapporteurs have also presented less influential impacts in briefly mentioned form in order to strengthen the results. On the other hand, for those assessments where the majority of impacts are only mentioned briefly and no quantification have been conducted, questions may be raised concerning the validity of the conclusions.

[8] We have employed the categories used in the overall EU Impact Assessment guidelines (European Commission 2005a)

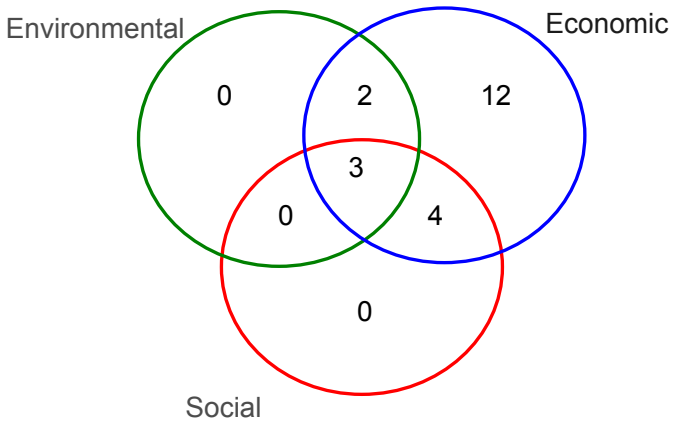
Table 3.6
Number of impacts analysed within environmental, economic, and social impacts

Impact	Environment	Economic	Social
Average number of impacts covered	0.4	4.0	0.2
Lowest/highest number of impacts covered	0 3	0 9	0 2
Average number of impacts with monetary quantification	0.1	1.7	0.1
Lowest/highest number of impacts with monetary quantification	0 1	0 7	0 1
Average number of impacts with other types of quantification	0.1	0.1	0.0
Lowest/highest number of impacts with other types of quantification	0 1	0 1	0 0
Average number of impacts with qualitative description	0.2	2.2	0.1
Lowest/highest number of impacts with qualitative description	0 3	0 9	0 1
Average number of impacts only briefly mentioned	0.1	1.8	0.3
Lowest/highest number of impacts only briefly mentioned	0 1	0 6	0 3

Note: N=22

Figure 3.2 shows that in 12 out of the 22 RRSs, only economic impacts have been covered, only three combine all three impact groups and just two cover both economic and environmental impacts. Four reports consider both economic and social impacts. None of the RRSs solely consider environmental or social impacts alone.

In general, the RRSs consider either economic impacts with some social and/or environmental aspects or no impacts at all. We cannot judge whether the exclusion of impacts was due to a deliberate decision or whether impacts in other areas have been overlooked.



N=22 (one RRS did not cover any impacts)

Figure 3.2 Risk Reduction Strategies with different combinations of environmental, economic and social impacts covered.

3.3.3 Level of detail of analysis

The characteristics of the RRSs differ according to the level of detail – i.e. degree of quantification – used to describe impacts. Ten reports include analysis where all impacts are qualitatively described. In seven of these reports, all impacts were described solely in briefly mentioned form. 12 reports included quantification of some impacts.

Table 3.7 provides an overview of the main categories covered by the 22 RRSs according to the level of detail of analysis of impacts. The impact categories which were not addressed were omitted from the table. Many categories were addressed only in a very few RRSs. The table differentiates between degrees of quantification according to the criteria listed in Box 2.1. Table 3.7 shows that in the case of economic impacts the majority of the analyses in the RRS were focused on operation and conduct of businesses and the impact on administrative costs for the chemical industry, as well as on the impact on specific regions and sectors when conducting monetised assessments of impacts. In contrast, impacts on competition, innovation, consumers, and public authorities were generally assessed more in qualitative terms, which may reflect difficulties in obtaining quantitative data on these aspects. In the case of environmental and social impacts, there are too few observations to warrant any generalisations, but concerning monetisation of environmental impacts only impacts on land use and waste were assessed. The assessments focused on impacts on end users in terms of consumers and households mainly contained qualitative or briefly mentioned description of impacts.

Table 3.7
Detail level of coverage of impacts

Impact	Briefly Mentioned (BM)	Qualitative	Quantitative	Monetised	Total (excl. BM)
Economic					
General	7	7		6	13
Operating cost and conduct of business	4	5		10	15
Administrative cost of business	5	2		9	11
Competitiveness, trade, and investment flow	6	5		5	10
Internal market competition	3	9		1	10
Innovation and research	1	5		3	8
Consumers and households	3	5	2	1	8
Specific regions and sectors	3	4		7	11
Third countries and international relations		2		1	3
Public authorities	10	7		2	9
Macroeconomic environment	2	1			1
Property rights	1				
Social					
General	1	1			1
Employment and labour market	3	1		2	3
Private sphere	1				0
Possible accidents	1				0
Crime, terrorism and security				1	1
Environmental					
Waste		2		1	3
Energy					0
Physical pollution/land use	1		2	1	3
Global warming and greenhouse gases		1			1
Acidification		1			1
Particle emission		1			1
Remediation	1				0

Note: N=22

In Table 3.7 the 62 impacts covered in the 22 RRS are presented in relation to type of impact and the detail level of coverage. Monetary assessment is mainly conducted for economic impacts. It also appears that more economic than environmental and social impacts were covered in all detail. This reflects the existence of very little hard evidence about the environmental damage caused by chemicals, which makes it difficult to monetise environmental impacts. This is somewhat parallel to the quantification of social implications derived from implementing risk reduction measures, as impacts are difficult to predict.

To inform decision-makers the best impacts – both positive and negative – must be covered in order to reflect the possible trade-offs involved in the risk reduction strategies. Figure 3.3 presents the distribution of positive and negative impacts covered by the RRS in each area of concern. There is a tendency principally for the negative impacts to be covered, but in the 'Economic' and 'Environmental' categories nearly half of RRSs also covered positive impacts. This result also reflects the observation from Table 3.7 that social impacts were not covered in more than a few RRSs.

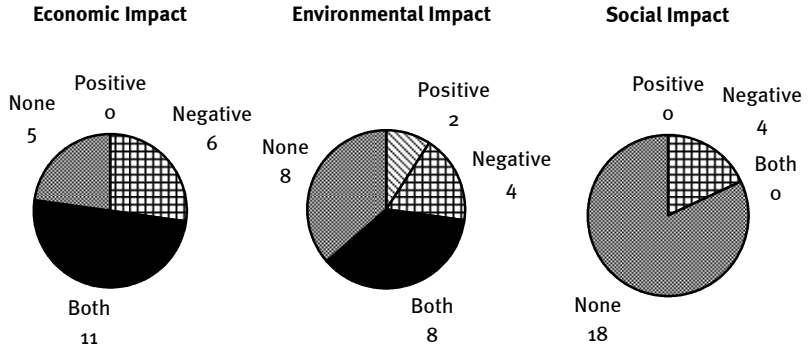


Figure 3.3. Number of RRSs covering both negative and positive impacts in different areas

According to the TGD on Development of Risk Reduction Strategies, the goal of the economic analysis is to identify the extent and distribution of the economic consequences that the promoted option/restriction is likely to have. This covers both the economic impact on industry and customers involved, and the indirect consequences (European Commission 1998). REACH requires focus not only on the direct economic impact (i.e. direct cost to the market) but also on the externalities, including costs imposed on third parties. Furthermore, where the regulation may impact on related markets, these should be considered.

3.3.4 Economic methodologies

The following analysis is derived from the 12 RRSs that included at least some monetised analyses of impacts. Table 3.8 presents an overview of the results for the economic methodology used in the analyses. Of the 12 RRSs that included monetarised results, four did not state which approach was used for their analysis, six used cost-benefit analysis (CBA), and two used cost-effectiveness analysis (CEA). The two CEAs used fixed targets such as total risk reduction and reduction below a certain set limit.

Table 3.8 also presents the different methods used by the Rapporteurs for economic quantification in terms of the applied methodology and data sources. Of the

12 RRSs with some monetisation, eight did not specify the economic method by which costs and benefits were obtained. Four of those were RRSs which did not state the economic methodology, and three were RRSs stating that they used a CBA approach.

None of the studies included a benefit valuation, but instead applied benefit transfer either of data obtained from studies using Contingent Valuation and/or Damage-Cost-Method. The use of data based on benefit transfer reflected how difficult and costly it is to undertake original benefit valuation studies, and the fact that such studies are not required in the TGD on Development of Risk Reduction Strategies. Three of the four Rapporteurs who used values based on benefit transfer reflect on the quality of the data.

Table 3.8
Methodological issues in 12 Risk Reduction Strategies with some monetised impacts

	Number of RRSs	Cost Benefit Analysis	Cost-Effectiveness Analysis	Not stated
Observed approach to economic analysis	12	6	2	4
Economic methods used in benefit valuation				
Not stated	8	3	1	4
Benefit transfer	4	3	1	
Contingent valuation	1	1	0	0
Damage-cost method	3	3	0	0
Data source				
Not stated	0	1	0	0
Use of pre-existing empirical data	11	5	2	4
- Quality of data addressed	4	2	2	0
- Underlying assumptions presented	2	2	0	0
Use of pre-existing model	5	2	2	1
- Quality of data addressed	2	1	1	0
- Underlying assumptions presented	3	1	2	0
New data have been collected	2	0	2	0
Stated analytical approach				
Cost-Effectiveness Analysis	3	2	1	
Cost-Benefit Analysis	7	3	2	2
Advantages and drawbacks	6	3	2	1
None	1	0	0	1

Note: N=12

Table 3.8 shows that of the 12 RRS with monetary quantification, only one did not specify whether or not pre-existing data were used. However, the others did not refer to their data sources. Only four of the RRSs using pre-existing data addressed the quality of the data collected, and only three of the 12 RRSs presented

the underlying assumptions for their data. Furthermore, five used a pre-existing model, and out of these, two reflect on both the quality and assumptions behind the model, while one reflects on the latter only.

In the lower part of Table 3.8, the observed approach to economic analysis used in the 12 assessments is compared to the approaches stated in the RRS objectives. It appears that there is not always a clear correspondence between the two, either for RRSs that state that a cost-effectiveness approach is taken, or for RRSs that state that a cost-benefit approach is taken. A stated objective of looking at analysis of 'advantages and drawbacks' indicates a cost-benefit analysis approach, but this was not always true. This may reflect either that the purpose of the economic analysis in the RRSs was not formulated clearly enough in the TGD on Development of Risk Reduction Strategies or in the RRSs themselves – or a lack of clarity on the part of analysts about the difference between cost-effectiveness and cost-benefit analysis.

Table 3.9 presents the geographical scope of analyses in RRSs using monetised assessments. It appears that half of the 12 RRSs based on an overall EU study were mainly rooted in generalised Member State studies. In fact, only two of all studies conducted the whole analysis as an EU based study. This is also reflected in the use of nationally decomposed values in nine of the 12 RRSs and in the 10 RRS that generalised case or country-specific values to the EU level (see Table 3.10). In general, such geographical extrapolation is fundamentally problematic to the extent population preferences and environmental composition differ across Europe (Lopdrup & Petersen 2007). How reasonable extrapolation is must be considered from case to case, which is outside the scope of this assessment.

Table 3.9
Geographical scope of economic analyses in 12 RRSs with some monetised impacts

Case study	4
Country/ Member State study	8
Overall EU study	6
Collection of separate studies	2

Note: N=12. Several RRSs have used multiple approaches and are counted more than once

Table 3.10
Data sources and use of data in 12 Risk Reduction Strategies with some monetised impacts

Use of national/regional decomposed values	9
Use of data from common European or US databases[a]	2
Extrapolisation of specific case study data to cover a wider scope	10
Use of generalised data to cover specific cases	1

Note: N=12, several RRSs have used multiple approaches and is counted more than once
[b] This could for example include 'ExternE' estimates

It may also be of relevance to assess the extent to which analyses with monetary quantification have taken a 'financial' or a 'welfare economic' perspective. As stated in Nielsen et al. (2006) this reflects whether the analysis mirrors the welfare effects of impacts rather than only the budgetary effects of impacts. This is important since there may be fundamental differences between the results in such analyses, e.g. in circumstances where market prices do not reflect the 'true' value of impacts. Since the economic analysis in the RRSs should assist in improving overall welfare of European Union citizens, it should employ an 'economic' perspective wherever possible. This is not reflected in the TGD on Development of Risk Reduction Strategies at present, but is mentioned in the preparatory work taking place under RIP 3.9. Of the 12 RRSs that conducted monetised economic assessments, four conducted welfare economic analysis, while seven (approx. two thirds) performed financial assessments.

3.4 Uncertainty, sensitivity and distributional analysis

With regard to coverage of issues related to uncertainty, Table 3.11 shows that only six of the 22 RRSs covered uncertainty to some degree. This contradicts the demands in the TGD on Development of Risk Reduction Strategies for conducting Risk Reduction Strategies, which recommends the inclusion of a systematic description of uncertainty in both quantitative and qualitative analysis. The degree to which uncertainty in the analyses is acknowledged is crucial to the strength of the reports. The analyses were basically ex-ante assessments of expected future outcomes. Hence the expected magnitude and the range of types of impacts will always be uncertain. In most cases, data for many possible impacts did not exist at the time the analysis was conducted, which clearly increased the need of Rapporteurs to be open about aspects of the analysis that could change with more knowledge. Analysis of uncertainty not only has the potential to provide decision-makers with a more informed decision basis – it can also point to areas where new or improved data are urgently needed.

Table 3.11
Issues of further information needs and uncertainty in the Risk Reduction Strategies

	Number of RRS	QN	QL	BM
Number of RRS	22	12	3	7
Issues of uncertainty covered	6	5	1	
- Quantitative coverage of uncertainty (e.g. sensitivity analysis)	0	0	0	0
- Qualitative coverage of uncertainty	3	3	0	0
- Uncertainty briefly mentioned	3	2	1	0
Uncertainty not covered	16	7	2	7

Note: N=22

A first step in dealing with uncertainties is to conduct sensitivity analysis. This is relevant in order to test which parameter values influence the result the most. However, none of the 22 RRSs included sensitivity analyses.

Of the 22 RRSs, 13 dealt with issues of distribution of effects between member states and regions. Table 3.12 shows with what level of detail this distributional analysis have been performed cross-tabulated with the corresponding level of overall detail of analysis of impacts in the RRSs. For the most part, distributional effects have been only briefly mentioned or covered by qualitative discussions, generally corresponding to the RRSs with the same level of detail of analysis of impacts.

Table 3.12
Considerations on distributional issues in the Risk Reduction Strategies

	Number of RRSs	QN	QL	BM
Number of RRS	22	12	3	7
Issues of distribution covered	13	9	1	3
- Quantitative coverage of distributional issues	2	2	0	0
- Qualitative coverage of distributional issues	3	2	1	0
- Distributional issues briefly mentioned	8	5	0	3

Note: N=22

3.5 Coverage of limitations of analyses

Of the ten RRS that did not conduct quantitative assessments, seven did not elaborate on why quantification was not performed. Those that did elaborate quoted lack of available data and uncertainty as the main causes for not quantifying. Of the 12 RRSs, which conducted quantification, five elaborated that in those parts of the assessment where quantification was not performed, the main reason was lack of data. Two RRSs pointed to reasons such as proportionality or the presence of an obvious case. These results are illustrated in Table 3.13, which presents the number of RRSs that consider the need for further collection of data or the conduction of quantitative/monetary analysis. Of the 22 RRSs, only four out of the 14 elaborating on the subject find the available information sufficient.

Eight RRSs recognise a need for further data collection and modelling. It is striking, however, that this covers six out of 12 RRSs that have already performed some quantification, but only two of the seven RRSs that only briefly mentioned impacts. We would expect that a higher need for quantification exists in instances where there are no quantitative data, except in areas considered non-important. It is therefore surprising that of the 10 RRSs that did not consider a need for further

collection of data, only seven considered impacts qualitatively or in briefly mentioned form.

Table 3.13
Considerations on issues of further information needs in the Risk Reduction Strategies

	Number of RRS	QN	QL	BM
Number of RRSs	22	12	3	7
Issues of further information, data gathering or quantification mentioned	14	10	2	2
- Information considered sufficient	4	3	1	0
- Information considered insufficient	8	6	0	2
- Sufficiency of information not considered	10	3	2	5

Note: N=22

Table 3-14 shows that only eight of the 22 RRS refer to limitations in the results based on data issues and uncertainty, and seven of these are reports that conducted quantitative assessments. This is striking since RRSs with all impacts only briefly mentioned would be expected to have severe limitations related to lack of data, but the RRSs that only briefly mention the various impacts of the risk reduction measures covered had a low degree of reflection on the implications of this approach for certainty of conclusions.

However, since monetisation or quantification also leads to uncertain results given data insufficiencies, it is natural to expect considerations about limitations of analysis in these instances too.

Table 3.14
Considerations on issues of limitations in the Risk Reduction Strategies

	Number of RRS	QN	QL	BM
Conclusion refers to limitations from lack of data and uncertainty	8	7	0	1

Note: N=22

The RRSs were assessed with respect to their ability to present limitations according to the chosen methodology, and to include considerations on areas not included in the main analysis. It is problematic that only about one third (8) of the reports touched upon the limitations of their assessment, and only one sixth (4) discussed the impact of the economic methodology on their results.

3.6 Does it matter who performs the Risk Reduction Strategies?

The Rapporteur Member States may be an influencing factor on what is included in a RRS because of the choice of methodology, level of detail of analysis, and general approach towards the RRS. Furthermore the choice of conducting the analysis themselves or using consultants may influence the outcome.

Table 3.15 presents the relationship between the degrees of quantification in relation to the Rapporteur Member States selected by the EU Commission. In the table, we have singled out the Rapporteur Member States responsible for RRSs where impacts were assessed solely in briefly mentioned form. In addition to this Table 3.16 presents the degree of quantification in the RRSs in relation to whether the analyst was a private consultancy or a government institution.

Table 3.15 shows that the Netherlands as Rapporteur has been responsible for the majority (five out of seven) of RRSs in the group with only briefly mentioned impacts. The other Rapporteurs producing such RRSs were Spain and the UK. All of these RRSs were written by government institutions (see Table 3.16).

Table 3.15
Rapporteur Member State and the degree of quantification

		Quantitative	Qualitative	Briefly Mentioned
Rapporteur Member State	Number of RRS	12	3	7
The Netherlands	6	1		5
United Kingdom	6	5		1
Spain	1			1
Others	9	6	3	

Note: N=22

Table 3.16 shows that all eight RRSs undertaken by private consultancies conducted monetary/quantitative assessment of impacts. Only four RRSs out of the 14 written by government institutions included a monetary/quantitative assessment (two from German and two from Finnish authorities). The single RRS from the Netherlands and the five RRSs from UK which included monetary analysis were all produced by private consultancies.

Table 3.16
Use of private consultancies and the degree of quantification

	Number of RRS	Quantitative	Qualitative	Briefly Mentioned
Number of RRS		12	3	7
Consultancies[a]	8	8		
Government institutions	14	4	3	7

Note: N=22
[a] Risk and Policy Analysis Limited, UK. (7) and Cowi A/S (1)

For the limited data material available in Table 3.16, the results indicate that private consultancies may be more likely to include monetary assessment and follow the guidelines set out in the TGD on Development of Risk Reduction Strategies. This may either reflect that only Risk Reduction Strategies considered as important are delegated to consultants, and hence treated in more detail or that consultancies are better equipped with expertise and know-how on conducting SEAs than public chemical agencies; or a combination of the two.

4. Economic analysis under US chemicals legislation

Main points

The US Environmental Protection Agency (US-EPA) has longstanding experience with conducting market-, impact- and cost-benefit assessments of chemical substances.

It is difficult to generalise from our six case studies of economic assessment in six US-EPA reports. However, the availability of data is also a principal constraint for SEA perfromance in the US. Similarly, the relatively limited availability of dose-response functions puts severe constraints on the valuation of benefits. With regard to costs, data from market studies, both public and proprietary, tend to be used more routinely than data provided by industry.

Uncertainty, sensitivity and overall limitations are generally discussed to a wider extent in our US sample than in the EU reports we have analysed.

This chapter analyses the US experience in order to see what lessons relevant for future SEA guidelines under REACH can be learned from US socio-economic analyses. US chemicals legislation is described in section 4.1. This is followed by a brief presentation of our sample of US-EPA reports used as cases (section 4.2). Section 4.3 rounds up the overall results from our analysis, and section 4.4 discusses these results in the US context and in relation the European results given in chapter 3.

4.1 The US chemicals legislation

Under the US Federal law, The Office of Pollution Prevention and Toxics (OPPT) at the US Environmental Protection Agency (US-EPA) has the authority under the Toxic Substances Control Act (TSCA) to undertake several types of regulatory and non-regulatory action in order to manage risks from chemical substances (Lee 2005), It is a Federal mandate statute (Battelle 2003). To accomplish its goals, OPPT has a strategic framework of statutory and regulatory tools as well as voluntary and partnership approaches (Battelle 2003).

TSCA regulates industrial chemicals. The Act includes a special provision requiring US-EPA to take specific measures to control risks from PCBs. Further, amendments have been made to address concerns about asbestos (1986), radon (1988) and lead (1992) (Brink et al. 2003). TSCA directs US-EPA to use the least burdensome option to reduce the risk to a level that is reasonable given the benefits provided by the chemical product or process (Brink et al. 2003; Tickner et al. 2005).

Box 4.1
The sections in the US Toxic Substances Control Act of relevance with respect to socio-economic analysis

The TSCA is divided into a number of sections (Tickner et al. 2005). With regard to our report the sections of most relevance are the following:

TSCA Title I, section 5: The Significant New Use Rule (SNUR) regulation restricts the use of either new or existing chemicals covered by the regulation. In the case of a new chemical, a Consent Order that places some type of restriction on the chemical substance is binding only on the manufacturer or importer of the substance. Consequently, after the Consent Order is signed, EPA may promulgate a SNUR under section 5 of TSCA that mimics the Consent Order to bind all other manufacturers and processors of the former new chemical to the terms and conditions contained in the Consent Order. EPA can also issue SNURs in the absence of a Consent Order as well as to cover existing chemicals. EPA can determine that a use of a chemical is a significant new use after considering several factors, including but not limited to the volume of the chemical substance, and the anticipated extent to which the use increases various exposure to humans or the environment associated with the new use. Information on manufacturing process, disposal method and health and environmental effects of the chemical substance must be submitted. No test data are required as a part of a SNUR or PMN (Goldman 2002). In 1994, 23971 PMNs had been reviewed and for about 10% of these, risk reduction measures had been required.

TSCA Title I, section 6: this section authorises US-EPA to issue regulations addressing the risk(s) from chemical substances already on the market. Under this Section of TSCA, the US-EPA may regulate the manufacture, import, processing, use, distribution and disposal of substances (Tickner et al. 2005).

TSCA Title IV, section 402: is the National Program Chemicals for reducing lead-based risk, a regulation under which US-EPA can test and manage the risk posed by lead. The work conducted and methodology used under TSCA Title IV is close to that in TSCA Title I, section 6 (Battelle 2003).

In 1994 the General Accounting Office (GAO) concluded that, in general the regulation under TSCA Title I, section 6 had been modest. Only five chemicals have been regulated under that section of the Act, and the Act itself requires only specific regulation of PCBs. In two cases, for PCBs and asbestos, US-EPA undertook a comprehensive analysis in order to regulate the substances, but in the asbestos case, many elements of the rule were overturned by a court decision (Goldman 2002).

4.1.1 Socio-economic assessment in US chemicals legislation

The economic analyses undertaken under TSCA are performed by the Economic & Policy Analysis Branch within OPPT. The economic work under TSCA is varied and dependent on the information needed for the specific risk management activity. Less comprehensive economic assessments (typically cost and burden assessments) are being developed for testing rules (TSCA Title I, section 4), Significant New Use Rules (SNUR) (TSCA Title I, section 5), and chemicals reporting and recordkeeping rules (TSCA Title I, section 8). More comprehensive economic assessments may be developed for risk management restrictions (TSCA Title I, section 6). Economic analysis required for TSCA section 6 regulations require a comprehensive socio-economic analysis. Further, before pursuing risk management options, a more in-depth understanding of the chemical substances markets is often useful. Three examples of market assessment studies developed by OPPT are included, they are: nickel carbonyl, mercury and PBDEs (Lee 2005), among many others.

Under TSCA Title I, section 6 and Title IV OPPT manages risks from the National Program Chemicals, which are regulations and policies designed to reduce risk from several specific substances. These are substances that are addressed through national policies and cover both substances with specific statutory requirements (PCBs and lead) and other multimedia pollutants of concern (e.g., asbestos, dioxin and mercury) (Battelle 2003).

A number of substances have been regulated under TSCA Title I, section 6 to date. The assessments were mainly conducted in 1970s or 80s. These were on CFCs (1977-78), PCBs (1978/79), dioxin (1980), metalworking fluids (1984), asbestos (1986-89), hexavalent chromium (1988-90), chlorine and chlorine derivates (1991), acrylamide and methylacrylamide grouts (1991) and lead fishing sinkers (1994). The last three have only been proposed. The asbestos rule was challenged in the Federal Court in 1991, and most of the rule was vacated and the acrylamide proposal was withdrawn 11 years later based on the development of effective and affordable personal protective equipment and a commitment by industry to promote use of this equipment and update its Safe Operating Practices Program (Battelle 2003; Tickner et al. 2005). There are no recent examples of TSCA Title I, section 6 economic analyses. Part of the reason for this is that the TSCA program has other sections and options that accomplish the specific goal of risk management without the time and resource consuming efforts involved in regulating under section 6. Further, there have been several occasions where the talk of proposing a TSCA Title I, section 6 regulation has led US-EPA to establish voluntary agreements between US-EPA and the industry (Lehman 2005). There are, however, recent examples of chemical specific regulation analyses which required more comprehen-

sive socio-economic analyses. Two examples (EPA 1996, EPA 1998 - see Table 4.1) come from TSCA Title IV- Lead Exposure Reduction.

There are two guidance documents that the US-EPA follows when conducting economic analysis: EPA's Guidelines for Preparing Economic Analysis (Battelle 2003), which were produced by economists from across the Agency and published by EPA's National Centre for Environmental Economics, and Circular A-4 by the Office of Management and Budget, which reviews significant US government regulations. Circular A-4 is designed to provide guidance to Federal agencies on the development of regulatory analysis, including cost-benefit analysis (Lee 2005). Circular A-4 has been produced as guidance on the development of regulatory analysis (socio-economic analysis) to implement Executive Order 12866 issued by the President of the US which "shall consider the environmental, economic and social impact of economically significant regulatory actions the administrators take or propose to take" (Goldman 2002).

4.2 Coverage of the US-cases

As explained in chapter 2, the assessed US-EPA reports were selected in order to mirror the EU legislation to the extent possible. Our analysis considers six official US-EPA reports comprising two reports under TSCA title IV, which is the National Program Chemicals for reducing lead-based risk, two reports under TSCA Title I, section 5 (See Box 4.1), and additionally two market assessments. The US-EPA reports included in our sample are presented in Table 4.1.

Table 4.1
Type and section of US-EPA reports analysed in this chapter

Type	Title
TSCA Title IV Regulatory Impact Analysis	EPA (1996): TSCA Title IV, Section 402(a) and 404: Target Housing and Child-Occupied Facilities. Final Rule. Regulatory Impact Analysis. EPA (1998): TSCA Title IV, §§402/404: Lead-based Paint Debris Management and Disposal. Proposed Rule. Economic Analysis.
TSCA title I, section 5 Implementation of the Significant New Use Rule (SNUR) legislation	EPA (2004): Economic Analysis of Expedited Significant New Use Rules for Four Glycol Esters EPS (2003): Economic Analysis of Expedited Significant New Use Rules for 65 Chemical Substances
Market assessments	EPAB (2002): Uses and Markets for Nickel Carbonyl EPA (2002): Market Analysis for the use of Polybrominated Diphenyl Ethers (PBDEs) as Flame Retardants – Focusing on Pentabromodiphenyl Ether (pentaBDE)

The first two EPA-reports analysed were conducted under TSCA Title IV. These were chosen in order to provide information on the thoroughness of such analysis, and to see to what degree these fulfil the requirements set for SEA under both US and EU chemicals legislation. The second set of reports does not require SEA, but considers the costs faced by the chemical industry in connection with the implementa-

tion of a Significant New Use Rule (SNUR). We include these reports in order to examine an analysis conducted when several chemical substances are expected to be subject to restrictive legislation simultaneously. The last set of reports includes smaller market assessments which are included in our sample because of their similarity to the EU RRS work on obtaining an economic overview of the relevant sector and sub-sectors of a given substance.

Ideally, a sample of SEAs carried out under US regulation which best mirrors EU legislation should include analyses carried out under TSCA Title I, section 6. However, because risk reduction is often achieved through either voluntary agreements or less cumbersome sections of TSCA, no TSCA Title I, section 6 assessments have been finalised (although several, for example acrylamide, have been proposed) by US-EPA since 1988 and therefore do not fulfil our selection criteria that our sample should reflect present-day practice.

4.3 Socio-economic analysis under the Toxic Substance Control Act

This section presents the findings from our case studies. The section is divided into three sub-sections, each presenting two similar cases. Each sub-section contains a small presentation of the cases followed by a brief table with our main findings and finally a short discussion.

4.3.1 Socio-economic analysis in the TSCA Title IV reports

Our two cases under the TSCA Title IV are presented in Box 4.2 and Box 4.3 respectively. Both cases concern the reduction of risk from lead-based paints, but they concern two different aspects of the abatement case. These two reports reflect the progress in policymaking in regard to abatement: the first report focuses on increased abatement of lead based paint, whereas the second report focuses on some of the risk reduction requirements to make the abatement more efficient.

Box 4.2
TSCA Title IV, Sections 402(a) and 404: Target Housing and Child-Occupied Facilities Final Rule Regulatory Impact Analysis.

This US-EPA report assesses the impacts on children's health from a strengthened abatement scheme for lead-based paints. The main analysis concerns the provision of stronger restrictions on lead abatement and improved training programs for workers, inspectors, and contractors within the lead paint abatement industry.

Here US-EPA conducts a very thorough analysis in which models are generated to calculate data and impacts in areas with unclear data. Focus is on analysing only the impact on risk reduction from the proposed program, and provides neither an assessment of alternative risk reduction strategies, nor a baseline scenario. This is based on the assumption that if the overall

benefit from total abatement is very much higher than the additional cost from the programme on a factor level, the program may be beneficial.

The assessment includes a market analysis of the market for training programs to predict the incremental cost of the proposed program. In addition, transition and monitoring costs are estimated to predict the impact on the public budget. Incremental costs from the additional workload based on the proposed work-practice standards are analysed based on weighted average cost figures supplied from industry information sources. All costs are provided as financial costs.

The field of beneficiaries is narrowed down principally to children aged zero to six living in houses or frequently occupying facilities or public buildings with lead-based paint present. The beneficiary group is chosen due to the availability of dose-response functions for lead and given the relatively severe impact of lead on these groups. Several other beneficiaries are mentioned but included only qualitatively in the analysis due to lack of data on negative impact.

Box 4.3
TSCA Title IV, §§402/404: Lead-based Paint Debris Management and Disposal. Proposed rule. Economic Analysis

This US-EPA analysis assesses cost savings pending from reducing waste disposal requirements for debris generated from abatement of lead-based paints. The main analysis assesses differences in costs of either disposing of lead-based paint waste using specialised equipment and extra-secure landfills, or using more ordinary equipment and ordinary construction and demolition landfills.

The cost assessments are conducted in quite detailed form, using national census and database material to model impacts for the three sectors that are presumed to work with lead-based paint abatement. The assessments focus on the proposed solution and do not include calculations on alternative strategies. A market assessment is conducted outlining those sectors which are most influenced by the law and a baseline calculation is conducted using the present regulation as benchmark. In addition, estimates of the costs of the new proposed alternative are calculated in regard to cost savings on e.g. transport, landfill, testing,, training, access limitations, and container requirements. Calculations are modelled using average financial cost figures from literature and industry.

The reduced risk reduction requirements lead to a predicted increase in the risk of lead leach migration to the groundwater. US-EPA uses a Monte Carlo approach to model the national distribution of peak receptor well concen-

tration over a 10,000 year horizon, estimating that the impact would be minimal.

Benefits are calculated as the cost savings between the two models and no monetary estimates are calculated on the increased lead leach mitigation to the environment, as the leached concentrations are calculated to be below one third of the maximum US lead contamination level. Qualitative assessments of the extent of expected increase in lead-based paint abatement due to lower costs are presented in relation to both public and private abatement.

The methodology used in the two TSCA Title IV reports appears similar in regard to estimating costs and conducting uncertainty and sensitivity assessments. Table 4.2 presents the main points of focus in our analysis.

Table 4.2
Assessment of TSCA Title IV examples

	EPA (1996): TSCA Title IV, Sections 402(a) and 404: Target Housing and Child-Occupied Facilities Final Rule Regulatory Impact Analysis	EPA (1998): TSCA Title IV, §§402/404: Lead-based Paint Debris Management and Disposal. Proposed Rule. Economic Analysis.
Methodology		
Objectives	Clearly presented	Clearly presented
Conclusion	The report contains a clear conclusion and clearly recommends options.	The report contains a clear summary and a clear conclusion on the recommended option.
Risk reduction options	One option is analysed in the main analysis considering several components.	One option analysed in detail and two additional options are assessed.
Baseline calculations	Uses incremental cost of the option but no use of baseline for benefits as the exposure changes from previous regulations were not available.	Baseline is calculated using the present regulation as benchmark.
Data	Data are collected through literature study and US survey databases. Estimates for the proposed program are taken from market analyses of existing programs in individual states, which bear resemblance to the proposed program. Data are extrapolated to provide national estimates.	Data are collected through literature searches, contact with industry and US census databases.
Impacts	Impacts are calculated using modelled estimates for target group and dose-response functions.	Impacts are estimated using a Monte Carlo approach.

Economic assessment	The report presents the economic background and theory for all models used, and discusses the assumptions for each model and their impacts on the results.	The report does not present the methods used.
Cost	Costs are calculated as incremental costs based on existing experience and data from industry.	Costs are calculated using data from industry and market data on firm size.
Benefits	Benefits are calculated for one specific group, and are estimated on the basis of loss of expected life earnings and schooling cost for children in non-abated homes. Willingness to Pay estimates are mentioned, but not included.	Benefits are calculated as cost savings. Additional benefits due to increased demand following the cost savings are assessed qualitatively.
Uncertainty/Sensitivity analysis	Several factors are analysed in regard to the sensitivity of the result based on changes in these factors. Cost, benefits and discount rate are included in the sensitivity analysis. For each factor, the variance in data and data availability are discussed.	Sensitivity analyses are undertaken with regard to several factors and assumptions, e.g. the strength of the baseline assumptions, cost of notification, number of States implementing the rules.
Discussion of impact on results of data availability/ quality	The report clearly discusses the impact of the data and assumptions on the result.	The report includes some discussions of the used data and assumptions

Both reports under TSCA Title IV in Table 4.2 are difficult to compare with the European Risk Reduction strategies, as the main focus of these reports has not been on the finding and assessment of risk reduction measures, but more on calculations relating to already specified risk reduction measures. The first report is difficult to compare to the EU reports as it presents calculations on a specific practical technique of controlling emission from a specific source to recipients. The second report is somewhat closer to the EU RRSs as it calculates the change in costs following a change in requirements relating to a risk reduction method.

4.3.2 TSCA Title I, section 5 reports

This section and section 4.3.3 include examples of economic analyses of TSCA regulations that due to the nature of these regulations do not need a comprehensive SEA. The Significant New Use Rule (SNUR) regulation restricts the use of either new or existing chemicals covered by the regulation as described in TSCA regulates industrial chemicals. The Act includes a special provision requiring US-EPA to take specific measures to control risks from PCBs. Further, amendments have been made to address concerns about asbestos (1986), radon (1988) and lead (1992) (Brink et al. 2003). TSCA directs US-EPA to use the least burdensome option to reduce the risk to a level that is reasonable given the benefits provided by the chemical product or process (Brink et al. 2003; Tickner et al. 2005).

The SNUR requires that manufacturers, importers, and processors of such substances notify EPA at least 90 days before beginning any activity that EPA has designated as a 'significant new use'. The notification required by SNURs allows EPA to prevent or limit potentially adverse exposure to, or effects from, the new use or application of the substance. Such a SNUR will require the submission of a Significant New Use Notification (SNUN) 90 days prior to commercial manufacture that does not conform to the conditions of the SNUR. The SNUR impact analyses analyse the costs faced by the affected firms that chose to take some type of follow-up action as a result of the SNUR. In this regard, the assessments differ substantially from the normal SEA requirements as they focus on different types of cost faced by the affected industry, such as transaction costs of submitting the application, costs of foregone profits during the SNUR process, or costs due to not engaging in the planned process. Thus, in these cost-based studies concerning the fixed rules of the SNUR, benefits are not included in the assessments. The two cases under the TSCA Title I, section 5 are presented in Box 4.4 and Box 4.5 respectively.

Box 4.4
Economic Analysis of Expedited Significant New Use Rules for 65 Chemical Substances.

This report concerns the inclusion of 65 different chemical substances under the SNUR legislation, by focusing on the economic impacts different options will be expected to have on manufacturing companies and importers. US-EPA assesses the costs of five different options faced by the industry for each substance, and presents an average cost based on this. Additionally, costs faced by exporters and transaction costs for monitoring and administration are briefly presented.

Box 4.5
Economic Analysis of Expedited Significant New Use Rules for Four Glycol Esters.

This report includes a short market assessment of the US market for the four glycol esters in question, presenting the major industries and importers of the substances as well as the production types and uses. The toxicity and historical toxic release trends are also briefly presented. In the analytical section, costs faced by the market are assessed in regard to producers, importers, exporters and monitoring authorities.

The methods used in the two SNUR impact assessments are closely related but differ in relation to their focus in the cases, one case assessing the impact of a few related substances and the other focusing on several different substances. Table 4.3 presents the main points we have chosen as our focus in the analysis.

Table 4.3
Assessment of TSCA Title I, section 5 examples

	EPA (2003): Economic Analysis of Expedited Significant New Use Rules for 65 Chemical Substances	EPA (2004): Economic Analysis of Expedited Significant New Use Rules for Four Glycol Ethers
Methodology		
Objectives	Present	Present
Conclusion	Present in summary of costs	Present in summary
Risk reduction options	Assesses five different strategies for firms to take in relation to the SNUR and presents the cost associated with each	Focus on two strategies (applying or stop producing) for firms to choose in relation to the SNUR. Other risk reduction measures are qualitatively assessed
Baseline calculations	Uses status quo as baseline and assesses incremental costs	Uses status quo as baseline and assesses incremental costs
Data	Data are obtained from literature studies, surveys and statistical sources. Test costs estimate based on industry market prices	Production and import/ export data obtained from industry. Commercial data from market research firms were used to describe market.
Impacts (hazardous)	Are not covered. Current security measures for each substance are presented	Briefly described with reference to other analyses, and description of substitutes
Economic assessment	Economic methods are presented and discussed	Economic methods are presented and discussed
Cost	Compliance costs of changed practices, foregone profits, and transaction costs in the application process, and costs of producing new data	Estimated for industry based on similar cases, monitoring and transaction costs estimated. Presentation of market trends
Benefits	n/a	n/a
Uncertainty/Sensitivity analysis	n/a	n/a
Discussion of impact on results of data availability/ quality	For cases where data is missing or difficult to obtain qualitative discussion on effect are conducted	Only to a minor extent

The SNUR reports estimate future administrative costs faced by companies utilising chemical substances under the legislation. When companies submit applications and get positive results, the costs are normally easily calculated. However, when companies forego their planned production, estimates of the foregone profit are more difficult to assess and have been left out of the assessments. Most data material has been obtained from national databases or surveys reflecting the focus on the reports as general impact assessments looking at a broader regulatory per spective. Only when costs of specific risk reduction strategies – e.g. safety equipment – have been considered in order to fulfil legal requirements, were data

obtained from the industry. In these cases, listed prices from leading companies were used.

4.3.3 Market assessment cases

Market assessments are reports that provide an overview of manufacturers, supply, demand and other characteristics of a chemical's markets in order to gain perspective for exposure assessments and provide information on initial thinking about risk management approaches (Lehman 2007). The two market assessments analysed here differ from each other, as one is mainly descriptive (as it presents the use and market for a substance), and the other takes a closer look into the possibilities for substituting a substance. The two cases on market assessments are presented respectively in Box 4.6 and Box 4.7.

Box 4.6
Uses and Markets for Nickel Carbonyl.

This report is a brief review of the literature and available data concerning the use and market for nickel carbonyl. It reviews data available to assess the scale of nickel carbonyl production in the US. Data are obtained from secondary sources such as commercial studies, company literature and newspaper searches. The presumed sites of production and use in the US are presented, and so are several cases where production sites have been in conflict with local interest groups.

Box 4.7
Market Analysis for the use of Polybrominated Diphenyl Ethers (PBDEs) as Flame Retardants – Focusing on Pentabromodiphenyl Ether (pentaBDE).

This market assessment focuses on the use of PentaBDEs at US production sites. The report presents several of the products where flame retardants are legally required, and it presents the suitability of PentaBDE to fulfil these requirements. Closely related PBDEs are also identified and assessed in terms of suitability for substitution, as are other alternative substances and technological solutions. The assessment systematically presents substance specifications, applications, and known toxicity of and comparisons with known marketable substitutes. The report also assesses foreign legal requirements and practices and qualitatively reflects on the applicability of these substitution practices in regard to the production methods in US companies. The analysis builds on a least cost analysis using the requirements of the US standards for flame control as the target.

The methods used in these two market assessments differ substantially. This is most probably due to the divergent focus of the two reports. Hence, a direct com-

parison is difficult. Table 4.4 presents the main points we have chosen to focus on in our analysis.

Table 4.4
Assessment of market assessment examples

	EPAB (2002): Uses and Markets for Nickel Carbonyl	EPA (2002): Market Analysis for the use of Polybrominated Diphenyl Ethers (PBDEs) as Flame Retardants – Focusing on Pentabromodiphenyl Ether (pentaBDE)
Methodology	Assessment of data from various sources	n/a
Objectives	n/a	n/a
Conclusion	n/a	n/a
Risk reduction options	Only present use is included	Thorough presentation of substance specifications and usability for known marketable substitutes. 12 alternatives are considered out of which three are screened out and assessed in regard to applicability and cost
Baseline calculations	n/a	Included
Data	Data are obtained through use of company literature and US inventory of present market	Data obtained from industry, previous studies, and literature and from US economic census
Impacts	Presents risk from the substances as it is described under US law	Presents the most important environmental and human toxicity issues for the range of PBDEs. Presents special cases of high concern
Economic assessment	n/a	Least Cost Analysis
Cost	n/a	Estimates cost for industry for three substitutes
Benefits	n/a	Fulfilment of US standards for flame control is set as benchmark (hence, benefits are not estimated)
Uncertainty/Sensitivity analysis	n/a	n/a
Discussion of impact on results of data availability/ quality	Discusses availability of data and the possibility of assessment of risk, but this is deemed outside the scope of the report	Difficulties in obtaining data from producers discussed

4.4 Patterns in use of socio-economic analysis under TSCA

In the following, the main experiences from the US cases will be presented and discussed and related to the corresponding findings from the EU-reports in chapter 3.

4.4.1 Data availability

Our small case-selection of reports conducted in relation to TSCA indicated that US-EPA uses several sources for obtaining data for its assessments. Internet and more informal sources may be used, particularly in reports that provide a quick overview of single chemical substances, whereas other types of data may be used in in-depth studies. Sources can range from US-EPA collected industry data or US-EPA estimates, to commercial market studies.

In the sample studies reviewed in this report, the US-EPA relied heavily on commercial market studies and only to a limited extent on data obtained directly from the companies in the chemical sector. When data were obtained through industry, these data were mainly price estimates for marketable goods, such as market prices for emission reduction technologies or for courses on abatement. The limited provision of data from industry reflects the way in which public data collection is organised in the US.[9] Lehman (2007) explains that even though the US EPA regulation opens the way for data collection from the public, the US requirements necessitate a lengthy clearance process prior to such data collection. US-EPA must weigh the costs of both the time and resources to collect such data against the anticipated value of such information in significantly strengthening the analysis, and thus, may choose to rely on alternative sources. Postle et al. (2006) describes that the industry may be reluctant to supply confidential information to a public agency. So the role of the US-EPA as the authority to grant or restrict the use of chemical substances under TSCA Title I, section 6 may reduce the incentives for chemical companies to voluntarily provide information.

Our study indicates that US-EPA to a large extent uses national censuses as a source for data input to models. The results of these models can then be used to conservatively predict the distribution of risk posed by the substance in question.

[9] US-EPA maintains an inventory of chemical substances manufactured and used commercially in the US. Starting in 1986, this inventory has been updated periodically through an Inventory Update Reporting (IUR) rule. These data provide one of US-EPA's primary data sources on industrial chemicals. By law, companies that manufacture or import chemicals on the TSCA Chemical Substances Inventory are required to report information about these chemicals; including type of substance, amount manufactured or imported, certain details about the chemical's manufacture, and other data. In 2003, EPA amended the IUR to expand reporting to include use and processing information in some cases.

In the two TSCA Title IV reports in our sample, both cost and risk distribution are modelled in this way.

Several of our US cases use extrapolation of data from specific States, with existing legislation or policies similar to the proposed options. Extrapolation of data from State level to national level may distort the overall results due to state-specific differences. Issues of distortion due to extrapolation of data are considered in most US cases where applicable. Furthermore, discussion of uncertainties, sensitivity and overall limitations to results are generally more developed in our US sample than in the EU reports we have analysed.

In those cases where products or services to reduce risk can be obtained in the present market, our cases show that US-EPA utilises this information in its models, for example, by using listed prices from major providers.

Both our study of the European Risk Reduction Strategies (RRS) and our coverage of the reports from US-EPA show that the availability of data is a principal factor affecting the conduct of SEA. As also observed by Postle et al. (2006), the fewer data available, the higher the tendency for impacts to be assessed in qualitative terms.

As the case study indicates, several of the US studies lack data from industry and use data from literature and national censuses instead. The use of general data to predict the impacts of specific risk reduction measures on specific industries weakens the result compared to analyses using industry-specific data. On the other hand, such data may provide better estimates on impacts on an aggregate level than data based on few industries extrapolated to a wider coverage. In contrast, most of the EU RRSs have obtained general cost data through cooperation with the producing industries and importers and from national consensus. In the RRSs, lack of data often arose from both unwillingness of companies to provide confidential data that could influence their competitive position, and from a tendency on the part of Rapporteurs to focus their analysis on their own country, subsequently generalising the results to a European level. All in all, there are pros and cons in the different approaches. These depend on the specific context and problem.

The disincentives of industry in the US to provide data to US EPA may serve as a warning to what to expect for EU Member States when conducting restriction processes under REACH. On the other hand, the possibility of importing and producing companies responding with their own material as third parties in the restriction process may potentially provide the European Chemical Agency with the necessary information.

Additionally, our analysis shows that there has been a lack of data availability in regard to predicting the costs of proposed risk reduction measures. Such data are not easily available as this requires the manufacturers to predict the incremental cost of fulfilling new theoretical requirements, often with the use of prices of technologies in immature markets. In this regard, the cost of abatement tends to be overestimated (Oosterhuis et al. 2006; Postle et al. 2006). This may reflect deliberate action by the data provider, or reduction of abatement prices once the market is developed for emission reduction. But the time frame for price development for abatement cost may be difficult to estimate beforehand, as discoveries of new technologies and the form of the learning curves are not easy to predict.

4.4.2 Dose-response functions

Our analysis has indicated that the availability of dose-response functions is essential for the calculation of risk and benefits related to substances and abatement strategies. In one report of our US sample, benefits were only monetised for those population groups where clear-cut dose-response functions are present, whereas the impact on the other populations groups at risk are only assessed qualitatively. In the European sample, several RRSs refrained from estimating the impact of substitution of those alternative substances that did not have clear dose-response functions, as the alternative substance could potentially be even more risky than that already being used. These RRSs therefore saw no need to estimate the alternative's technical and economical feasibility.

The question of the availability of dose-response functions may be reduced in the future as REACH requires dose-response functions to be assessed for substances produced or imported in quantities above 1000 tonnes per year, and that these data become publicly available.[10]

4.4.3 Assessing the market for chemicals

Several of the US cases include assessments of the market for the substance in question. This section focuses on all of these generally and on the market assessments specifically. The US-EPA cases show that market assessments may be quite easily undertaken in a system where information is readily available through economic censuses and national statistics. In a European context, tax and import/export information as well as recordkeeping requirements in the legislation can provide such information. However, the results of such data will be of a general nature, and thus even though they may be adequate for a market assessment they may distort the result if used alone in a SEA. More specific and precise market assessments need specific information on production volumes from producers

[10] For chemicals produced in smaller amounts, the problem of lack of dose-response data is expected to persist.

and importers, but even though such data is available for US-EPA through the TSCA inventory, it is typically confidential and used for internal evaluation but not used in public reports unless adequately masked (Lehman 2007). In our sample the TSCA inventory has not been used. US-EPA estimates market values based on proprietary market studies, public data sources and data from the producers, such as net income, key production parameters, world market share, or by taking sources from where data is available and extrapolating the results to the whole market. Seen in this perspective, it may appear as if the US-EPA may face more difficulties than the European Rapporteurs in conducting market assessments for chemical substances.

4.4.4 Financial or economic cost in US sample

Our sample shows that US-EPA has included financial cost estimates for parameters such as costs of application, transaction costs, monitoring costs, costs of protection gear, and testing costs. All these cost types are directly influenced by US-EPA requirements. Costs of foregone profits were not covered in several of the cases. Again, this may reflect a difficulty of the US-EPA in obtaining producer-specific data.

Due to the requirements in the US legislation for regulations that are considered 'major', US-EPA must assess whether there is a significant impact on a substantial number of small enterprises and assess this impact. All but one assessment in our sample have included these considerations. However, the level of detail of these reflections differs between the reports, varying from in-depth treatment of the SME question (in three reports) to a very limited treatment in the remainder. This may reflect the wide diversity of types of reports we have included in our sample and the level of importance the different dimensions are being given in the various types of assessment produced by US-EPA.

Our analysis shows that the ability to estimate the cost of promoted risk reduction measures depends on the availability of data on existing practices and predictions of cost for fulfilling new requirements. Such estimates are most easily obtained through cooperation with industry as in the European RRSs. In relation to REACH, most of the data required to estimate costs may be supplied from the manufacturers to the Agency in the form of raw data or analyses generated by industry. The data provision requirements in REACH will give the Agency the basic data to conduct in-depth market assessments. Furthermore, as firms will have to apply for authorisation they will be required to provide estimates of their future costs for reducing risks posed by the substance in question, giving the Agency an insight into the expected general order of magnitude of various types of costs for different strategies. As mentioned previously, it will not necessarily be an easy task for the ECHA to evaluate the quality of cost estimates supplied by manufacturers and

importers, since these will have incentives for supplying cost estimates that will help them promote their own interests.

4.4.5 Difficulties of estimating benefits in monetary terms

Benefits from proposed risk reduction measures are only assessed in one of the six economic reports in our US sample. This may be due to the composition of the sample and does not necessarily reflect the general pattern in the work of US-EPA. Benefit estimates are only assessed in the report on lead abatement in target housing and child-occupied facilities. The other report on lead based paint focused only on cost savings. For these analyses it was therefore not a requirement to include benefit estimates. Neither market assessments nor SNUR reports consider benefits as this is not required.

The report on lead abatement in target housing and child-occupied facilities calculates the benefits from reducing hazardous emission from lead-based paint. Focus is on children aged zero to six as dose-response functions are thoroughly described for this population. The main impact of lead on this subgroup is in the form of intelligence reduction, an impact for which it was difficult to assign monetary values at the time the analysis was conducted. The authors of this report acknowledge that the most optimal benefit estimates would have been Willingness to Pay (WTP) estimates of the populations' preference for reducing loss of intellect in small children. Such estimates were not included due to the cost and difficulties associated with obtaining them. In the light of this, benefits were calculated using estimates for lost life earnings and increased school expenses due to decreased intellect. These two types of benefit calculations can generally be considered second-best approaches that can provide lower-edge estimates. The benefits were only calculated for a minor part of the actual population facing the risk induced by the lead based paint while other beneficiaries were presented in the report and the impact on these were treated in qualitative terms.

The 'second-best' approach to calculating benefit estimates in the report on lead abatement in target housing and child-occupied facilities reflects the difficulties and costs involved in undertaking SEAs of chemicals.

5. What relevance for future guidelines for socio-economic assessment under REACH?

Main Points

Broadly, our review of the previous use of socio-economic analysis (SEA) of chemical substances in the EU and the US provides insights into the possible main constraints to further development of the use of SEA under REACH could be. This, in turn, is relevant information for the SEA guidelines to be produced.

However, detailed SEA guidelines may not be enough to ensure improved SEA. Data availability is a key requirement for enabling detailed analysis of both costs and benefits. Also, coverage in guidelines does not necessarily imply that guidelines are followed in practice. Thus, there may be a need for *mandatory* coverage of important issues in the future REACH guidelines – e.g. uncertainty and limitations.

In this chapter we discuss what can be learned from the observations made from our study of SEA in European RRSs (chapter 3) and US-EPA TSCA cases (chapter 4). Our perspective is to identify areas of concern that should be taken into account in future socio-economic analyses under REACH in order to encourage the use of economic analyses designed to support decision-making. We will review and discuss our major findings, and use them to provide recommendations for improved analyses, suggest tools, and address limitations.

5.1 Socio-economic analysis of chemical substances – how much to expect?

The focus on SEA under REACH, and the underlying idea of incorporating socio-economic considerations in the authorisation and restriction process is positive in every sense. It gives several interest groups the possibility to supply inputs to the process, and it has the potential to provide decision-makers with a more informed decision basis via a more systematic appraisal of costs and benefits.

Although a higher focus on providing the data necessary for socio-economic analysis has the potential to improve the quality of decisions under REACH, previous experience from the US and EU indicates that decision-makers and interest groups should be aware of some of the limitations and constraints of conducting comprehensive SEAs. The theoretical state-of-the-art SEA of managing risks from chemical substances cannot be attained easily in practice without primary data collection and additional risk assessment work. On the other hand, when SEAs and other

economic analyses are sized proportionately to the problem, substantial information of value to decision-makers can be provided.

The observations that there are barriers for improved SEAs in practice should not be used to discourage further emphasis on SEA. Rather, it should be used to induce humility regarding the limitations of the SEAs as performed in practice, and to identify the critical areas where more methodological and empirical work can improve analyses so that future SEAs of chemical substances can be improved. Based on our analysis, we have identified a number of critical areas important for the quality of SEA under REACH. These are described in the following.

5.1.1 Objectives and conclusions

The inclusion of clear objectives and conclusions in reports should be considered very important in future SEAs under REACH. Our observations from previous experience in the EU showed that this has not generally been the case in previous work. This may be because the RRSs were conducted as part of the 793/93/EEC chemicals Regulation and thus the objective might have been seen as given. But in future SEAs the setting of the scope through clear objectives and conclusions should be seen as a matter of minimal discipline that will allow the European CHemical Agency (ECHA) to verify a minimum of quality and make approaches somewhat comparable.

5.1.2 Data availability and quality

Quantification of benefits from risk reduction in terms of monetised estimates relies on the availability of underlying risk data. If these data do not exist and cannot be generated in reliable form, performing an ambitious SEA is not realistic. Furthermore, even if risk data do exist, it is important that these data are in a form directly transferable to economic analysis, and that reliable economic valuation estimates related to specific health states exist. With regard to the former, it is important that risk data are not available simply as qualitative risk ratios, but rather in the form of dose-response functions and estimates of levels of exposure and population exposed. With regard to the latter, economic valuation of changes in health status remains a controversial area. This does not mean that such estimates should not be aimed at – indeed such valuation is important to allow comparison of unlike risk situations. However, care should be taken with interpretation of such estimates.

The experience from previous SEAs undertaken under EU as well as US regulation as documented by this report indicates that there are large gaps in availability of such data. Particularly in the EU, there are very few examples of comprehensive monetised estimates of impacts, and there is a wide diversity in methodology and data types used in the instances where it has been applied. This may be due to

- Too little emphasis on data collection in general
- Lack of overall coordination of data collection (both in terms of collection of data in databases, but also in terms of consistency in methodology and coverage of population groups)
- Too little coordination between pure risk assessments and the data needs of socio-economic analyses (the form of data needed)

In the absence of data it is understandable that the best available data are used, and that more qualitative rather than quantitative analyses are undertaken instead. However, in order to improve the certainty of results and to facilitate a learning process, it is important to be open about the limitations of the data and methodology, and about how a given analysis differs from the 'optimal' analysis.

In the context of REACH this points to an important role for the ECHA to organise databases of dose-response functions and to ensure consistent use of methodology. Secondly, it points to the need for clear guidelines and to monitoring of adherence to these guidelines. Thirdly, it points to the need for coordination between the guidelines for socio-economic assessment and the guidelines for risk assessment, in order to ensure that the data delivered by the risk assessment procedure are as directly applicable to the socio-economic analysis as possible. This would improve the quality of core data to be used in socio-economic analysis.

Having pointed to the need for overall consistency in SEA in practice, it is important to recognise that the vast diversity in the possible types of risks[11] and risk reduction strategies means that there will always be some need for flexibility in choice of method and the type of data needed. This underlines the need for proportionality with respect to the theoretically best possible information base and what is practically feasible to obtain.

Moreover, the coarse nature of estimates based on national censuses may be subject to criticism in regard to their statistical liability, but, on the other hand, if they are used conservatively, they can still provide important information on possible order of magnitude of impacts.

[11] Chemical risk may range from chemicals with a direct toxic impact on human health and chemicals with long term impacts on eco-systems through bio-accumulation both which may or may not come from the same point of origin or be spread trough the same sources. Furthermore, there is the possibility of 'cocktail' effects with several chemicals impacting e.g. health at the same time.

5.2 Estimating costs

5.2.1 Financial and welfare-economic costs

As we have observed in chapters 3 and 4, costs have generally been analysed in financial terms and not from a 'welfare-economic' viewpoint. For analyses focused on describing markets for chemicals this is perfectly natural since these analyses have a business-focus. However, as underlined in section 3.3, this is not satisfactory in a socio-*economic* analysis, since a comparison of overall costs and benefits to society requires an 'economic' and not a financial view to be taken.

Guidelines should clearly specify that the estimate of economic costs is preferred and that estimates that only include financial costs are less comprehensive. The subject was covered in the work undertaken under RIP 3.9, and cost estimates in future SEA guidelines can be expected to be required to be given in economic terms.

However, financial estimates may still be used in cost estimates of risk reduction strategies or substitution with alternative substances provided by producers or importers. Financial focus on their own internal costs would be expected from private-sector players, with only limited consideration of overall economic impacts on society. In such cases it will be a challenge for the ECHA to make sure that financial costs are not treated as economic estimates in the evaluation of such analyses.

5.2.2 Balance between benefits and costs

The results in Figure 3.3 indicate that there may be disproportionate focus on calculating negative effects of a risk reduction measure (e.g. costs) compared with positive aspects (e.g. health-related or environmental benefits). In this context, it could be argued that many of the analyses included in the sample have in practice taken a cost-effectiveness perspective – i.e. focus in many EU RRSs was to reduce a given trait of a substance. Thus, a non-economic benefit target has already been set in these instances. The results also show that there may be an imbalance between coverage of economic compared to social and environmental costs and benefits. A balanced socio-economic analysis should cover all relevant costs and benefits. Of course, this pattern may reflect that there are more important economic impacts than there are social or environmental impacts, but it is equally possible that direct cost estimates for industry are easier to estimate for the Rapporteur than indirect benefit values such as uncertain future savings on health care or saved aesthetic environmental values. This would also fit the pattern of a focus on financial cost estimates that are more easily and directly observable, rather than on more relevant – but more difficult – estimates of economic costs.

The fact that more analyses tend to focus on the costs of risk reduction measures than on benefits may also reflect some very tangible barriers to quantification of benefits – an issue we will focus on in the next section. However, this is no excuse for not treating benefits qualitatively. Even when we account for qualitative treatment of benefits, our analysis of treatment of costs and benefits still points to a disproportionately high focus on costs. It should be emphasised that the idea behind SEA under REACH is fundamentally benefit- and not cost-driven as it is the requirement for societal benefits that should drive the policymaker to regulate in the first place. Thus, social benefit calculations should be the starting point. Hence, other sub-dimensions such as the costs to business - although of course also important in the overall picture - should be seen as secondary in such a stepwise reasoning.

Another relevant issue is the use of an appropriate baseline. In order to make relevant comparisons of incremental costs and benefits related to different options, it is vital that a realistic baseline is employed. This is not always the case, as exemplified in both EU and US cases.

As mentioned above, our report has shown that many analyses take a 'cost-effectiveness' perspective instead of a 'cost-benefit' perspective. CEA is useful for determining the least cost means of achieving pre-set targets, but on the other hand cannot answer the question whether a given reduction of risk will be an overall net benefit to society. Given that the overall purpose of socio-economic analysis under REACH is to assess whether the costs of restriction outweigh the benefits it is important to emphasise that CEA in that respect has severe limitations.

5.3 Estimating benefits

Despite our limited sample of cases, it is still quite clear from our report that the data to calculate specific benefit estimates are in general not readily available, either for the EU Rapporteurs or the US-EPA. E.g. – as can be seen from Figures 3.1 to 3.4 – few environmental impacts have been covered. This may reflect a lack of hard evidence about the environmental damage caused by chemicals, and a lack of economic valuation studies of these damages – something already pointed out in several assessments of the benefits of REACH as a whole. However, as pointed out in section 2.3.1, the low number of environmental impacts considered may also relate to the fact that the RRSs are based on a Risk Assessment Report in which effects on human health and environment may have been more thoroughly elaborated. As for valuation of environmental damages, in the few instances in our sample where such estimates have been used, they have been obtained through benefit-transfer or damage-cost methods – and only in one case through a Willingness To Pay (WTP) analysis. This is confirmed directly in several of our cases, where it is stated that there is a lack of benefit data to cover the complexity of risk

that different chemical substances may pose. Another reason stated is resource constraints against conducting specific benefit valuation for each case.

Compared to legislation prior to REACH there is now cause for more optimism in this area, since there is increased focus on obtaining more and better data in the new REACH legislation. This should be a good first step towards better benefit assessments. However, it would be naive to expect that first-rate benefit estimates will be easily available for all relevant analyses under REACH. The reason for this is the time and resource-consuming nature of conducting benefit valuation, not to mention the methodological barriers to obtaining reliable estimates and the importance of availability of useful risk data (in section 5.2). Present best practices for SEA are so far from the optimum, that the increased emphasis under REACH should rather be seen as a welcome and highly needed first move, instead of one that will have immediate and wide-ranging results.

A more likely scenario – and one which could be more constructive in the shorter term – is the application of a second-best solution where alterntatively, benefit estimates predominantly rely on the constructive use of benefit-transfer techniques. A more systematic collection of data on a European scale, and a careful use of these data to estimate effects for other population groups would give more immediate results in terms of improving the inclusion of benefit data in SEAs of chemical substances. There are many limitations to such techniques, not least if applied indiscriminately across very dissimilar population groups. Furthermore, the issue of meaningful comparison of welfare effects across EU borders also entails major practical and theoretical challenges (Lopdrup & Petersen 2007).

The difficulties involved in estimating benefits of a given substance should be taken into consideration when the European Chemical Agency handles cases. As many analyses carried out by producers or importers could be expected to use cost-effectiveness methods, it should be seen as the responsibility of the European Chemical Agency to balance these cost-estimates with the benefit side so as to enable the most efficient solutions to be chosen.

As the risk posed by chemical substances ranges over many different impacts, from reducing the fertility in e.g. amphibious populations in small pond systems to inflicting serious health issues on human beings, analysts face the challenge of assessing the benefit estimates that fits the exact type of impacts posed by the substance. This could be done through WTP analysis where the Rapporteur assesses the overall population's willingness to pay for reducing the impact on a given population. Analyses based on WTP (e.g. 'contingent valuation') themselves have some limitations, not least when impacts are complex or not well understood, but better alternative valuation methodologies do not exist at present.

5.4 Uncertainty, sensitivity and distributional analysis

Our results indicated that very few of the cases in our sample performed uncertainty analysis, and none of the European RRSs conducted sensitivity analyses of the results. This is problematic in the sense that both types of analyses were prescribed by the TGD on Development of Risk Reduction Strategies, and because such analyses can supply important information about how solid the conclusions of the analysis are, and where further knowledge to substantiate (or challenge) results is most needed. This point is also stressed by Nielsen et al. (2006), but it is even more important in an area like this, where so many sources of uncertainty exist. This is not an impossible task. Our sample of cases from US-EPA showed that both clarity with respect to uncertainty and the performance of sensitivity assessment are possible in relation to socio-economic analysis of chemicals.

Analysis of distributional consequences of regulation can generally be important information for decision makers (Lopdrup & Petersen 2007), but it is apparent from our sample that such analysis has been virtually absent. Again, lack of data is a credible explanation, since quantification is not easy in this area. Thus, a proportional approach would often be to rely on qualitative coverage, not least if the alternative is no coverage.

5.5 Coverage of limitations

As presented in section 3.5, our analysis of experience from EU RRSs indicates that too few of the Rapporteurs consider the limitations of their analyses in regard to the chosen model, assumptions, and the data available. Limitations constitute important information, and hence lack of knowledge of these limitations reduces the value of the analysis. In regard to uncertainty, this is problematic since the TGD on Development of Risk Reduction Strategies requires that the RRSs clearly state limitations that may be influencing the results. The US experience indicates that this is also an area where the EU could learn from US-EPA. The US analyses included in our sample are generally comparably more transparent with respect to limitations – and this does not reduce the applicability of their results.

Under REACH it becomes important to have increased focus on limitations, which may in turn also make Rapporteurs and the ECHA more likely to turn attention towards solutions that can reduce limitations.

5.6 Substitution

The assessment of substitution substances or technologies is a very complex and demanding area. The coverage of substitution included in the EU RRSs and in some of our US cases, as documented in this report, could be said to be sufficient,

but this does not mean that the analytical approaches with respect to alternatives have been adequate. With regard to effects on human health and the environment, and on technical feasibility, many analyses of substitutes covered were quite detailed. However, most substitution analyses did not consider the economic aspects of the promoted alternatives. Analysing substitutes is very complex and demanding as each alternative should preferably be scrutinised in the same way as the original substance in order to present a consistent comparison. The TGD on Development of Risk Reduction Strategies includes one page of requirements for assessing alternatives, promoting a stepwise approach to screen options. A stepwise approach can indeed be helpful, but this does not preclude more detailed analysis when alternative substances are in fact realistic options. A consistent baseline is also very important in such comparative analyses.

In one of the analysed cases, alternatives which were both technically sound (in regard to end-use) and potentially sound economically were disregarded, because they did not fit into the present production lines on the home market. In such questions the European Chemical Agency should at least consider the costs of changing the present production systems, or formulate a substitution plan over a fixed timeline, as well as considering the wider implications outside the industry of a single country.

5.7 Proportionality

As discussed in Chapter 2, socio-economic analysis of chemicals should ideally cover all relevant policy options and all relevant impacts of these options. As observed in this report, this is not always done in practice. Often, only few options – including substitutes – are analysed, and only few general impact categories are covered, and often only qualitatively. This may be warranted if:

- The options and impacts covered are indeed the most important ones, and proportionality considerations demand a realistic scope of the analysis and/or
- Lack of data precludes the analysis of all possible options and impacts

If applicable, these reasons ought to be explicitly stated in the reports. This is important in order to demonstrate that exclusion of options or impacts is not due to neglect but to conscious deliberation about proportionality or lack of knowledge. This would allow more explicit communication of the analysis limitations emanating from a low number of options or impacts covered, or from low level of detail of analysis of impacts. Furthermore, this could facilitate the identification of areas where more detailed analysis or new data could best support the decision-making process.

Specifically, as promoted in Nielsen et al. (2006), this could take the form of a requirement for SEA to include statements like the following, which could invite challenges from stakeholders: "We are not aware of any evidence suggesting impacts on X, so this issue was not investigated further".

It is important to be aware that any decision to accept a lower detail level of analysis due to proportionality considerations will have implications for uncertainty. Thus, the attention devoted to issues of uncertainty ought to be ensured at all levels of proportionality. Given that proportionality may imply a low degree of quantification of impacts, this attention to uncertainty may not be possible in the form of quantitative sensitivity and uncertainty analyses. However, it is important that the impact on the certainty of results of not quantifying results is discussed thoroughly. Our observations in this report suggest a tendency in RRSs performed under EC regulation 793/93 towards devoting less energy on addressing uncertainty issues in the reports where impacts have been covered only to a modest degree. This needs attention in the final guidelines to prevent such 'disproportional' coverage of uncertainty in economic analyses performed under REACH.

6. Conclusion

In this report we have identified a number of areas where socio-economic analysis (SEA) of chemicals as previously carried out in practice face a number of challenges.

Hopefully, the wider use of socio-economic analysis under REACH will in itself lead to improved socio-economic analysis quality, thereby strengthening the decision making basis for authorisation and restriction of chemical substances.

This is a goal worth pursuing. However, it should be clear that this will not simply materialise automatically. Many of the observations we have made based on past experience can be expected to persist under a new system, unless specific action is taken.

The main challenges we have observed in this report are:

- Improved access to useful risk data e.g. through coordination of data and data needs between risk assessments and SEAs
- Improved assess to cost and market data
- Improved methodologies for measuring and expressing benefits in order to 'translate' them into monetary form
- More systematic coverage of all relevant options and impacts in detailed quantitative form
- More systematic coverage of uncertainty, assumptions and the ensuing limitations

The first step in dealing with these challenges will be to ensure that they are explicitly addressed in the guidelines for socio-economic analysis and risk assessment under REACH. Taking proportionality into consideration, it is of course also important that guidelines are realistic and operational. With this in mind, a review of whether the guidelines have been successful in facilitating sufficient quality of analysis in the areas pointed out above would be desirable after a few years of experience. This would also provide input to a revised decision whether minimum standards in certain areas of analysis should be necessary.

However, it is not just a question of ensuring that these issues are covered in the guidelines. As demonstrated in this report with regard to uncertainty analysis and coverage of limitations, the inclusion of guidelines on a specific method is no guarantee of its use in practice. It may be necessary to make a point in the guidelines of communicating the importance of such analysis even to the extent of making it a requirement that the ECHA would then have to monitor. Such increased emphasis is particularly needed in the areas of uncertainty analysis and communication of limitations of analyses.

What is required is that future SEAs have a sound logic and well applied methodology that makes the important assumptions visible for the ECHA. Even with this in place, stakeholders would still be expected to have a wide discretion for how to carry out SEAs in practice – and there would still be considerable quality verification left for the ECHA. Here, a helpful potential minimum requirement for applications would be for the underlying analyses to undergo obligatory independent quality assessment.

We recommend that the ECHA explicitly focus on the inclusion of both uncertainty and sensitivity analysis, and explicitly consider assumptions and limitations in socio-economic analysis received by the ECHA from producers and third parties when issuing an authorisation or a restriction. These limitations should also be clear from the conclusions of such reports.

This report also has its limitations. We do not claim to cover a representative sample of SEAs as carried out under US chemicals legislation, and with respect to EU, we have focused on SEAs carried out under the Existing Chemical Substance Regulation 793/93. Furthermore, by applying a checklist to the EU sample we have been able to identify areas of concern, but not to assess quality of the reports as such. Our observations and conclusions should be seen in this light.

The increased emphasis on socio-economic analysis under REACH has the potential to provide decision makers with a better understanding of the implications of their policy choices. However, even with more resources devoted to analyses, ensuring a balanced, and truly well-informed socio-economic analysis prior to authorisation and restriction of chemicals under REACH is bound to remain a complicated task.

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Appendix 1: Sample of EU Risk Reduction Strategies

Report Name	CAS Number	Num-ber	Year
Analysis of the Advanges and Drawbacks of Banning Azo-Dyes and Products of Azo-dyes, Final Report, July 1997	90-04-0	1	1997
O-Anisidine: Risk Reduction, Elaboration of a Risk Reduction Strategy under existing Substances Regulation (EEC) No 793/93, 2002	90-04-0	1	2002
Risk reduction strategy for the application of 1,2,4-trichlorobenzene in the EU	120-82-1	2	?
Risk reduction strategy, Toluene, Draft	108-88-3	3	?
Risk reduction strategy, hydrogen peroxide h202, Draft March 2003	7722-84-1	4	2003
Risk reduction Strategy Tert-butyl methyl ether,draft of May, 2001	1634-04-4	5	2001
Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Octabromodiphenyl Ether	32536-52-0	6	2002
2-Propenoic acid (acrylic acid) Methyl Methacrylate. Strategy for limiting Risk - Environment	79-10-7	7	2002
2-Propenoic Acid, 2-Methyl (Methacrylic acid) (Acrylic acid) Strategy for Limiting Risks - workers	79-41-4	8	2002
2-Methyl-2-propenoic acid, methyl ester (methyl Methacrylate) Strategy For Limiting Risks	80-62-6	9	2002
Risk reduction strategy for 1,4-Dioxane	123-91-1	10	2000
The Advanges and Drawbacks of Introducing Community-wide Restrictions on the Marketing & Use of 2-(2.butoxyethoxy) Ethanol (DEGBE)	112-34-5	11	2001
2-(2-Methoxyethoxy)Ethanol Strategy For Limiting Risk	111-77-3	12	?
Risk Reduction Strategy for Acrolein	107-02-8	13	1999
Risk Reduction Strategy for Dimethyl Sulphate	77-78-1	14	1998
Hydrogen Fluoride Strategy For Limiting Risks, draft	7664-39-3	15	2001
Risk Reduction strategy for acrylonitrile	107-13-1	16	2000
Risk reduction strategy for acetonitrile	75-05-8	17	?
risk reduction strategy and analysis of advantages and drawbacks for Acrylamide	79-06-1	18	2000
Proposed Controls on the Use of Short Chain Length Chlorinated Paraffins (SCCPs)	85535-84-8	19	
Risk Reduction Strategy For 1,3- Butadiene	106-99-0	20	2002
Pentabromodiphenyl Ether: Regulatory Impact Assessment	32534-81-9	21	?
Risk Reduction strategy and Analysis of Advantages and Drawbacks for Pentabromodiphenyl Ether	32534-81-9	21	2000
Nonylphenol Regulatory Impact Assessment	25154-52-3	22	2002
Nyphenol Risk Reduction Strategy	25154-52-3	22	2000
Phenol, 4-nonyl-, branched	84852-15-3	23	?

Appendix 2: Sample of US-EPA reports

Title	Year	Author	Main issue
TSCA Title IV, Sections 402(a) and 404: Target Housing and child-Occupied Facilities Final Rule Regulatory Impact Analysis	1996	US-EPA regulatory impact branch	The report analyses the cost benefits and impacts of regulations under §§404: Training of workers Standards for products Timely substitution
TSCA Title IV, §§402/404: Lead-based paint debris management and disposal proposed rule economic analysis.	1998):	US-EPA, Lehman T. et al.	Cost effectiveness assessment of reducing the reguirements for handling, transportation and storage of debris coated with lead based paint. Cost estimated for several industry sectors.
Market Analysis for the use of Polybrominated Diphenyl Ethers (PBDEs) as flame retardents – Focusing on Pentabromodiphenyl Ether (pentaBDE)	2002	US-EPA	Marked analysis of the use of PentaBDE and similar analysis of potentially viable substitutes.
Uses and markets for Nickel Carbonyl	2002	US-EPA environment and policy branch	Small review of the sources, uses and markets for nickel carbonyl. Done as a quick review of available data
Economic Analysis of Expedited significant new use rules for four glycol ethers "Does not contain TSCA CBI"	2004	US-EPA environment and policy branch	SNUR on specification that manufacturing and importing 2-EE, 2-EEA, 2-ME and 2-MEA for use in consumer products constitutes a Significant New Use. Presentation of companies' option concerning the SNUR.
Economic analysis of expected significant new rules for 65 chemical substances "Does not contain TSCA CBI"	2003	US-EPA environment and policy branch	Analysis of cost of applying Snur for 65 chemicals under the PMV review process.

Appendix 3: Categories of risk reduction measures

The overall aggregate, average, minimum and maximum number of risk reduction measures for each step for all 22 Risk Reduction Strategies (RRSs) is presented in the first table. A total of 138 Existing Measures, 225 Analysed Measures and 85 Proposed Measures are covered by the 22 RRSs. The average number of risk reduction measures is 6.3 Existing Measures, 10,2 Analysed Measures and 3.9 Proposed Measures for each RRS. The range of measures for each step is 0 to 14 for Existing Measures, 0 to 28 for Analysed Measures and 0 to 13 for Proposed Measures. The second table presents the distribution of measures in RRSs for each step, and shows that a relatively high number of the RRSs consider relatively few potential risk reduction measures.

Average number of risk reduction measures present in the Risk Reduction Strategies

Measures	Aggregate	Average	min	max
Existing	138	6,3	0	13
Analysed	225	10,2	0	28
Proposed	85	3,9	0	14

Note: N=22

Distribution of Risk Reduction Strategies based on numbers of risk reduction measures

Measures	0	1-4	5-8	9-12	>13	Avr.
Existing	2	6	6	5	2	6.3
Analysed	3	3	8	7	5	10,2
Proposed	3	11	3	0	1	3.9

Note: N=22

59 different risk reduction measures were identified In the RRSs. In order to simplify this analysis, these 59 risk reduction measures have been classified into nine crude general categories, thereby reducing the probability that measures covered by the same regulation will be counted twice. The table below presents a comprehensive overview of the risk reduction measures in each category. The categories are broad and cover several specific risk reduction measures and regulations.

This means that the total number of measures can be narrowed down to a reduced number within different categories (with a maximum of nine categories covered in a given RRS).

In the analysis of Analysed Measures we have drawn a distinction between the total number of risk reduction measures covered in the analysis and the newly suggested measures. The latter comprise all measures analysed less than those measures already analysed under existing measures. So in order not to count analysed measures twice - both as existing measures and promoted measures - we will in the following only present measures analysed exclusively under step two (see Box 3.5).

Category	Existing risk reduction measures	New risk reduction measures
Restriction on end use - Restriction of marketing and use of substances either as a total ban or restriction to use of substances only under certain conditions	Restriction on marketing and use (Directive 76/769/EEC)	Restriction on marketing and use (in EU under Directive 76/769/EEC) Specified conditions for use Restricting the marketing and use to specific applications Restricting to industrial/professional use Specified conditions for use Limiting overall quantity available to each user
Product safety - Reduction of risk from the use or disposal of end use products, by setting standards for chemical composition or construction of the product	Concentration in cosmetic products (Directive 76/768/EEC) Directive on General Product Safety 892/59/EEC)	Maximum concentration in formulation Directive on General Product Safety 892/59/EEC) - Rapid Alert System (RAPEX) Technical standards
Reduction of emission levels - Commission set standards on the emission level of substances in contaminating discharge or on the substance concentration in the environment. The risk reduction measures vary from set standards to requirements of BAT and handling of waste	IPPC Directive (96/61/EC) - Permits for operation IPPC Directive (96/61/EC) - Emission limits IPPC Directive (96/61/EC) - Best Available Technology (BAT) and Reference Documents (BREF) Directive 76/464/EEC, 90/415/EEC amending 86/280/EEC. Emissions to the aquatic environment. Most appropriate measures and techniques, incl. emission limits and environmental quality standards Environmental quality standards Water Framework Directive 2000/60/EC 98/83/EC. Quality of drinking water VOC-directive 99/13/EEC Transport regulation (EU Directive 96/49/EG + 94/55/EC) 91/689/EEC on Hazardous Waste 2001/118/EC Waste Management 80/86/EEC on Protection of Groundwater Ecological criteria (96/304/EC) Directive 80/68/EEC	Integrated pollution prevention and control (IPPC) 96/61/EEC - Production permits Integrated pollution prevention and control (IPPC) 96/61/EEC - Emission limit values (ELV) (air, WWTP, etc.) Integrated pollution prevention and control (IPPC) 96/61/EEC - Best available Technology (BAT) and Reference Documents (BREF) Emission standards / Emission limit values (ELV) Environmental quality standards Water Framework Directive 2000/60/EC - emission control Water Framework Directive 2000/60/EC - Environmental quality standards VOC directive 99/13/EEC - Emission limits Sector specific guideline for handling Reuse and recycling Criteria for storage and storage control Groundwater and drinking water protection As low as technical possible (ALATP) Environmental permits Emission monitoring Environmental monitoring 'End-of pipe' control
Improved safety information - The Commission sets standards for the amount of information needed in order to reduce the risk of using the product by end users or industry workers.	Safety Data Sheets (SDS) (in EU under Directive 67/548/EEC, 91/155/EEC, 93/112/EEC and 88/379/EEC) Classification, packaging and labelling (in EU under Directive 67/548/EEC) Preparation Directive (1999/45/EC)	Safety Data Sheets (SDS) (In EU under Directive 67/548/EEC, 91/155/EEC, 93/112/EEC and 88/379/EEC) Classification, packaging and labelling (in EU under Directive 67/548/EEC) Preparation Directive (1999/45/EC) Improve use instructions/inform users on appropriate use Use instructions

Improved worker safety - Risk reduction measures applied to reduce the overall risk to workers handling dangerous substances. Either by limiting contact with substance, technical requirements for facilities or for protection equipment	Occupational Exposure Limits (OEL) (in EU under Directive 98/24/EC, 96/94/EC and 2000/39/EC) Personal Protection Equipment (PPE) (in EU under Directive 89/656/EEC) Protection of workers related to exposure to carcinogens at work (90/394/EEC, 1999/38/EC) Training of workers Protection of the health and safety of workers from risk related to chemical agents at work (98/24/EC and 80/1107/EEC) Measures to encourage improvement in safety and health of workers (Framework Directive 89/391/EC) Permissible exposure limits (PELs)	Occupational Exposure Limits (OEL) (in EU under Directive 98/24/EC, 96/94/EC and 2000/39/EC) Use or improved use of Personal Protection Equipment (PPE) (in EU under Directive 89/656/EEC) Carcinogenic Agents Directive 90/394/EEC Training Protection of the health and safety of workers from risk related to chemical agents at work (98/24/EC and 80/1107/EEC) - indicative occupational exposure limit values Workers Protection Directive 89/391/EEC Chemicals Agents Directive 98/24/EEC Use or improved use of personal protective equipment for consumers Biological monitoring / medical survey of workers / health surveillance Improved ventilation Technical measures
Commission control of eco-management - Voluntary schemes for industry to manufacture product with reduced environmental impact following criteria laid down by the Commission	Self-classification Voluntary industry guidelines Local voluntary agreements with industry Ecolabelling for textile products (1999/178/EC) Eco-management audit scheme	Certification system/quality assurance Good Management Practice (GMP) under ISO standards Licensing of operators Licensing vendors
Alternative substances -Substitution of the risk-posing substance with other substances or other materials		Re-design of product design Remediation Use of stabilising additives Substitution/replacement
Technical substitution -Substitution of the risk posing substance with other technologies or production forms		Technical requirements Best Available Technology (BAT) Procedural measures (incl. cleaning of equipment) Re-design of process/Use of clean technology Maintenance of or replacement of old equipment
National policies - Individual EU Member States may have more restrictive legislation than the EU and such regulations are used as guidelines for the promoted options	National policies	National legislation

Appendix 4: Checklist Used

CAS No:
Internal No:

Checklist Part I

Review of Economic Analysis of Chemical Regulation

1. Basic information

Title and date of the Report:

Does the title of the report refer to the methods used in the report and if yes, which?

Responsible country:

Length of report (pages) excl. summary and annexes?

Annual Production of chemical:	

Major use(s) of chemical and use(s) that gives cause to adverse affects, if different from major use(s):	

	yes	no	n.a.	If yes, who?	page(s)
Is the report produced by a consultant?					

How was the report obtained:	yes	no	n.a.	Comments
On the homepage of the competent authority?				
Through contact with the competent authority?				
Others?, if yes which?				

	yes	no	n.a.	Comments	page(s)
Have any guideline been applied in the assessment?					
The technical guidance document (TGD) on development of risk reduction strategies (RRS)?					
Risk Benefit analysis of Hazardous Substances?					
Risk Benefit Analysis of Existing Substances?					
The OECD Guidance for conducting retrospective studies on socio-economic analysis?					
EU-guideline for Impact Assessment?					
The EPA Guideline for Preparing Economic Analysis?					
Others? If Yes, which:					

What is the regulatory framework or policy context?	yes	no	n.a.	Comments	page(s)
Directive 793/93/EEC on existing substances in the EU					
Other? If yes, which?					

	yes	no	n.a.	Comments?	page(s)
Have stakeholders been involved					

2. Problem statement

	yes	no	Comments?	page(s)
Is a clear objective defined?				
If yes, is the objective defined as:				
Assessment of the economic impact				
Assessment of effectiveness, practicalities and monitaribility				
Assessment of the regulatory impact				
Assessment of the impact on business				
Assessment of the impact on small businesses				
Assessment of the costs				
Assessment of the costs of compliance Administrative compliance cost Business compliance costs				
Assessment of how to achieve the target at least costs				
Assessment of how to achieve most units of target at least costs				
Assessment of advantages and drawbacks				
Assessment of Costs and Benefit				
Assessment of positive and negative impacts				
Assessment of Risk and Benefit?				
Assessment of impact?				
Macro-economic modelling (input-output analysis or general equilibrium model)				
Multi criteria analysis, assessment of the Life Cycle Analysis or analysis of DPSIR				
Others?, if yes, which?				

3. Analysis

	yes	no	Comments/Description	page(s)
Is it exclusively an analysis of policy in place				

Options

Have existing measures in place been analysed	yes	no	Comments/Description	page(s)
If yes, what are these and how have they been analysed: Briefly mentioned (**Bm**), Explicit delimitation (**D**), Qualitative discussion (**Ql**), Quantification (**Qn**) [If **Qn** is marked, please fill in part III of checklist], or Monetarisation (**M**) [If **M** is marked, please fill in part II of checklist]				
Restriction on marketing and use (Directive 76/769/EEC)				
Concentration in cosmetic products (directive 76/768/EEC)				
Preparation Directive (1999/45/EC)				
Classification, packaging and labelling (in EU under directive 67/548/EEC)				
Safety Data Sheets (SDS) (in EU under Directive 67/548/EEC, 91/155/EEC, 93/112/EEC and 88/379/EEC)				
Directive on General Product Safety 892/59/EEC)				
Occupational Exposure Limits (OEL) (in EU under Directive 98/24/EC, 96/94/EC and 2000/39/EC) Permissible exposure limits (PELs)				

Personal Protection Equipment (PPE) (in EU under directive 89/656/EEC)				
Protection of workers related to exposure to carcinogens at work (90/394/EEC, 1999/38/EC)				
Protection of the health and safety of workers from risk related to chemical agents at work (98/24/EC and 80/1107/EEC)				
Measures to encourage improvement in safety and health of workers (Framework directive 89/391/EC)				
Training of workers				
IPPC Directive (96/61/EC) permits for operation emission limits best available technology (BAT) and reference documents (BREF)				
Directive 76/464/EEC, 90/415/EEC amending 86/280/EEC Emmission to the aquatic environment. Most appropriate measures and techniques, incl. Emmission limits and Environmental quality standards				
VOC-directive 99/13/EEC				
Ecological criteria (96/304/EC)				
Eco-management audit scheme				
Environmental quality standrads				
Ecolabelling for textile products (1999/178/EC)				
Transport regulation (EU directive 96/49/EG + 94/55/EC)				
Directive 80/68/EEC				
2001/118/EC Waste Management				
91/689/EEC on Hazardous Waste				
Water Framework Directive 2000/60/EC				
80/86/EEC protection of groundwater				
98/83/EC quality of drinking water				
National Policies				
Voluntary industry guidelines				
Local voluntary agreements with industry				
Other?				

Further Risk Reduction Measures				
	yes	**no**	**Comments/Description**	**page(s)**
Are further risk reduction options listed (in addition to existing measures)?				
Is it explained how the different options have been identified?				

If yes or if relevant:				
	yes	**no**	**Comments/Description**	**page(s)**
Have short-listing been applied (i.e. is a long list of options used as a starting point for a shorter)?				
Have criteria been applied?				
It is evident which measures are relevant or Some measures are clearly not appropriate				
According to the LCA/Risk Assessment, it is evident				
Other?				

	yes	**no**	**Comments/Description**	**page(s)**
Have short-listing been applied (i.e. is a long list of options used as a starting point for a shorter)?				

Have criteria been applied?				
It is evident which measures are relevant or Some measures are clearly not appropriate				
According to the LCA/Risk Assessment, it is evident				
Other?				

	yes	**no**	**Comments/Description**	**page(s)**
Has a clear distinction been made between measures and implementation?				

Type of implementation				
What types of implementation have been considered?	**yes**	**no**	**Comments/Description**	**page(s)**
Regulation				
Economic instruments (such as taxes, subsidies tradable permits)				
Voluntary agreements				
Information programme				
Infrastructure investments				
Other?				

The Further Risk Reduction Measures				
Which policy options are on the list for consideration?	**yes**	**no**	**Comments/If other, which?**	**page(s)**
Restriction on marketing and use (in EU under directive 76/769/EEC)				
Preparation Directive (1999/45/EC)				
Directive on General Product Safety 892/59/EEC) - Rapid Alert System (RAPEX)				
Safety Data Sheets (SDS) (In EU under Directive 67/548/EEC, 91/155/EEC, 93/112/EEC and 88/379/EEC)				
Integrated pollution prevention and control (IPPC) 96/61/EEC Production permits Emission limit values (ELV) (air, WWTP, etc.) Best available technology (BAT) and reference documents (BREF)				
Occupational Exposure Limits (OEL) (in EU under Directive 98/24/EC, 96/94/EC and 2000/39/EC)				
Protection of the health and safety of workers from risk related to chemical agents at work (98/24/EC and 80/1107/EEC) - indicative occupational exposure limit values				
Workers Protection Directive 89/391/EEC				
Chemicals Agents Directive 98/24/EEC				
Carcinogenic Agents Directive 90/394/EEC				
Emission standards / Emission limit values (ELV)				
Classification, packaging and labelling (in EU under directive 67/548/EEC)				
Use or improved use of Personal Protection Equipment (PPE) (in EU under directive 89/656/EEC)				
Good Management Practice (GMP) under ISO standards				
Improve use instructions/inform users on appropriate use				
Licensing of operators				

Licensing vendors				
VOC directive 99/13/EEC Emission limits				
Biological monitoring / medical survey of workers / health surveillance				
Environmental quality standards				
Environmental monitoring				
Water Framewoek Directive 2000/60/EC emission control environmental quality standrads				
Substitution/replacement				
National legislation				
Others?				

	yes	**no**	**Comments**	**page(s)**
Are other types of options considered (e.g. obtions for firms etc.)				
If yes, are they:				
Others?				

How many alternative options are considered (apart from existing regulation)?	

If only one policy option is considered (apart from current regulation), what (if any) arguments are used for not considering alternative policy options (or discarding them early)?

	yes	**no**	**Comments/Description**	**page(s)**
Proportionality (e.g. a minor regulation)				
Lack of data				
Widespread agreement on policy option by stakeholders				
Late in the process of decision making				
Difficult				
Not compatible with other legislation				
Case obvious				
None				
Other? If yes, please state				

4. What areas of impact are covered by the economic analysis of the chemical regulation?

Which impacts have been addressed and how (apart from existing regulation)?
Briefly mentioned (**Bm**), Explicit delimitation (**D**), Qualitative discussion (**Ql**), Quantification (**Qn**) [If **Qn** is marked, please fill in part III of checklist], or Monetarisation (**M**) [If **M** is marked, please fill in part II of checklist]

Impact	**How addressed?**	**Comments / description (e.g. reason for no quantification or no monetisation)**	**Time frame: short run (SR), medium run 3-10 years (MR), long run (LR)**	**- Page(s) - Refer. to part II & III of checklist**
Economic				
General				
Technical feasible for businesses?				
Buisness impact (in general)				
Administrative cost on businesses (businesses compliance costs)				
Transitional costs (such as training, reorganisation)				
Operating cost (such as conduct of business)				
Capital costs (such as investments in e.g. new technologies)				
Infoon the number of companies/organisations affected? (Do not				

fill in part III)				
Impact on small and medium size companies				
competition and competitiveness				
Trade issues incl. export – import				
Innovation and research/technological development				
The level of use of raw materials and availability of raw materials				
Product quality				
Product availability				
Product price				
Product variation				
Trend in use or production of product				
Analysis of the affected sector				
Analysis of related sectors				
Third countries and international obligations				
Public authorities (such as health care, clean up or waste treatment)				
The macroeconomic environment				
Timing/timescale				
Existing stocks				
Other (please state)				
Social				
General				
Employment and labour market (e.g. joblosses)				
Standards and rights related to job quality				
Equality of treatment and opportunities, non-discrimination				
Private sphere				
Ethic issues				
Public health and safety				
Possible accidents				
Crime, Terrorism and Security				
Access to and effects on social protection, health and educational systems				
In line with existing commitments				
Other (please state)				
Environment (other than the risk assessment)				
Waste				
Energy				
Physical pollution/landuse				
Global warming				
Acidification				
Ozone depleetion (stratospheric)				
Ozone formation (atmospheric)				
CO emission				
HC emissions				
PAH emissions				
Particles emissions				
NOx emissions				
Fire and explosion safety				
Remediation				

Other, if yes please state				

	yes	no	Comments/Description	page(s)
Have any substitutes been addressed?				
If yes, how have it been addressed: Briefly mentioned (Bm), Explicit delimitation (D), Qualitative discussion (Ql), Quantification (Qn) [If Qn is marked, please fill in part III of checklist], or Monetarisation (M) [If M is marked, please fill in part II of checklist]				
Are the adverse effects of the substitutes on human health or the environment addressed?				
Is the economic impact of the substitutes addressed? Such as e.g. the market for substitutes				
Is the social impact of the substitutes addressed?				
Technical feasibility				
Other				

	yes	no	Comments/Description	page(s)
Are direct costs to the Administration (EU, MS or USEPA) budget of the options estimated? (i.e. administrative implementation costs) If yes, please describe: Briefly mentioned (Bm), Explicit delimitation (D), Qualitative discussion (Ql), Quantification (Qn) [If Qn is marked, please fill in part III of checklist], or Monetarisation (M) [If M is marked, please fill in part II of checklist]				

General observation on the analysis

	yes	no	n.a.	Comments	page(s)
Are issues of further information /data gathering / quantification / modelling mentioned? (if mentioned in the risk assessment (i – conclusion)) it does not count as yes in this question)					

If yes, issues of further information are mentioned

	yes	no	n.a.	Comments/Description	page(s)
Are issues of further information /data gathering / quantification / modelling mentioned? (if mentioned in the risk assessment (i – conclusion)) it does not count as yes in this question)					
Is current available information considered sufficient?					
Is a need for further information /data gathering / quantification / modelling identified? (Please describe which)					

	yes	no	Comments/Description	page(s)
Has a specific distinction been made between financial and economic costs				
Are the impacts categorised as direct, indirect and unintended				
Other				

Overall coverage of positive and negative impacts
(not including 'no policy' and 'business as usual' options):

	Positive	Negative	Both	None	Comments
Economic					
Social					
Environmental or human health besides the risk assessment					

What overall perspectives on problems are covered, apart from impacts only 'briefly mentioned'? (Please circle - more than one answer possible): *Short / medium / Long run / n.a.*

For the options where no physical or monetary quantification has been performed
What (if any) arguments are used for not using either physical or monetary quantification?

	yes	no	Comments Description	page(s)
Proportionality? (e.g. minor regulation)				
Lack of data?				
Data access?				
Uncertainty?				
Difficult?				
Case is obvious (e.g. high benefits, low costs)				
Severity of the risk?				
None				
Marketing and use is not considered as an option				
Other? If yes, please state				

Has the assessment been performed on a case base, on sector base or on separate studies (if any, please indicate which)	yes	no	n.a.		page

5. Distributional analysis

	yes	no	Comments/Description	Page
Are distribution issues addressed?				

Detail of distribution analysis:
Briefly mentioned (**Bm**), Explicit delimitation (**D**), Qualitative discussion (**Ql**), Quantification (**Qn**), or Monetarisation (**M**)

Distribution issues?	Economic	Social	Environment and human health	pages
Geographical distribution Between member states Between regions EU vs. outside EU				
Income distribution?				
Gender distribution?				
Ethnic distribution?				
Large enterprises versus small and medium size enterprises				
Other?				

6. Uncertainty/Sensitivity?

Uncertainty

	yes	no	Comments/Description	Page
Is uncertainty with respect to assumptions or data addressed?				

If yes, uncertainty issues are addressed, how is this done and what categories of variables are covered?

	Briefly mentioned (**Bm**), Explicit delimitation (**D**), Qualitative discussion (**Ql**), Quantification (**Qn**), or Monetarisation (**M**)	Comments/Description	page(s)
Economic			
Social			
Environmental			

and human health			

Other variables? If yes, please state:

	yes	no	Comments/Description	Page
Is there a justification for choice of assumptions / data covered by uncertainty analysis?				

If no, uncertainty issues are not addressed:

Is a justification for not addressing sensitivity put forward? If yes, please state:

Sensitivity

	yes	no	Comments/Description	Page
Are sensitivity issues addressed				

If yes, uncertainty issues are addressed, how is this done and what categories of variables are covered?

	Briefly mentioned (Bm), Explicit delimitation (D), Qualitative discussion (Ql), Quantification (Qn), or Monetarisation (M)	Comments/Description	page(s)
Economic			
Social			
Environmental and human health			

Other variables? If yes, please state:

	yes	no	Comments/Description	Page
Is there a justification for choice of assumptions / data covered by sensitivity analysis?				

Is likelihood of changes in parameter variables assessed?

	yes	no	Comments/Description	Page
Best estimates + inner/outer bounds?				
Probability distributions?				
Other, please state				

If no, sensitivity issues are not addressed:

Is a justification for not addressing sensitivity put forward? If yes, please state:

7. Quality

	yes	no	n.a.	Comments	page(s)
Does the analysis appear transparent? (subjective)					
Does the analysis appear reproducible? (subjective)					
Are relevant reference quoted?					
Is review by stakeholders performed					
Is a peer or expert review performed					

8. Conclusion of the report

	yes	no	Comments/Description	Page
Is there a conclusion concerning policy options?				

If relevant

Which type of implementation have been cho-	yes	no	Comments/Description	page(s)

sen?				
Regulation				
Economic instruments (such as taxes, subsidies tradable permits)				
Voluntary agreements				
Information programme				
Infrastructure investments				
Other?				

If relevant

Which policy options was chosen?	**yes**	**no**	**Comments/If other, which?**	**page(s)**
Restriction on marketing and use (Directive 76/769/EEC)				
Concentration in cosmetic products (directive 76/768/EEC)				
Preparation Directive (1999/45/EC)				
Classification, packaging and labelling (in EU under directive 67/548/EEC)				
Safety Data Sheets (SDS) (in EU under Directive 67/548/EEC, 91/155/EEC, 93/112/EEC and 88/379/EEC)				
Directive on General Product Safety 892/59/EEC)				
Occupational Exposure Limits (OEL) (in EU under Directive 98/24/EC, 96/94/EC and 2000/39/EC) Permissible exposure limits (PELs)				
Personal Protection Equipment (PPE) (in EU under directive 89/656/EEC)				
Protection of workers related to exposure to carcinogens at work (90/394/EEC, 1999/38/EC)				
Protection of the health and safety of workers from risk related to chemical agents at work (98/24/EC and 80/1107/EEC)				
Measures to encourage improvement in safety and health of workers (Framework directive 89/391/EC)				
Training of workers				
IPPC Directive (96/61/EC) permits for operation emission limits best available technology (BAT) and reference documents (BREF)				
Directive 76/464/EEC, 90/415/EEC amending 86/280/EEC Emmission to the aquatic environment. Most appropriate measures and techniques, incl. Emmission limits and Environmental quality standards				
VOC-directive 99/13/EEC				
Ecological criteria (96/304/EC)				
Eco-management audit scheme				
Environmental quality standrads				
Ecolabelling for textile products (1999/178/EC)				
Transport regulation (EU directive 96/49/EG + 94/55/EC)				
Directive 80/68/EEC				
2001/118/EC Waste Management				
91/689/EEC on Hazardous Waste				
Water Framework Directive 2000/60/EC				
80/86/EEC protection of groundwater				

98/83/EC quality of drinking water				
National Policies				
Voluntary industry guidelines				
Local voluntary agreements with industry				
Licensing of operators				
Licensing vendors				
Good Management Practice (GMP) under ISO standards				
Substitution/replacement				
Chemicals Agents Directive 98/24/EEC				
Carcinogenic Agents Directive 90/394/EEC				

Concerning the conclusion

	yes	**no**	**Comments/Description**	**page(s)**
Is there a clear conclusion?				
If yes or if relevant anyway				
Is there a clear recommendation of one or more policy option?				
Is the way of selecting a policy option described?				
Are decision criteria applied?				
Is the conclusion clearly related to the objective described in the table on p. 3				
Does the conclusion refer to the economic methodology applied?				
Does the conclusion refer to other types of assessments or economic methodologies?				
Does the conclusion refer to precautionary principle?				
Does the conclusion make specific reference to environmental costs or benefits?				
Does conclusion make specific reference to social costs or benefits?				
Does conclusion make specific reference to economic costs or benefits?				
Does conclusion refer to possible tradeoffs between environmental / social / economic areas?				
Is/are break-even point(s) identified?				
Does conclusion refer to possible synergies between environmental / social / economic areas (e.g. by referring to Lisbon Agenda)?				
Does the conclusion refer to effectiveness, practicality and monitaribility				
Does the conclusions refer to disproportion				
Does the conclusion refer to limitations to analysis due to choice of policy options covered?				
Does the conclusion refer to limitations to analysis due to underlying assumptions?				
Does the conclusion refer to limitations to analysis due to incomplete information or availability of data				
Does the conclusion refer to limitations to the analysis due to uncertainty				
Other arguments/areas referred to in conclusion? If yes, please state				

Does the conclusion make use of: qualitative arguments (Ql), direct quantification (Qn), or direct monetarisation (M)?

	yes	**no**	**n.a.**	**Comments**	**page(s)**
Is a clear distinction made between a financial ('budget') perspective and an economic ('welfare-economic') perspective in the conclusion?					

If yes, a clear distinction is made,

Does the conclusion involve use (whether quantitative or qualitative) of
financial costs and benefits (F),
economic (welfare economic) costs and benefits (E),
use of both (B)

Comments for internal use:

Overall quality of Economic analysis, please circle (subjective assessment for internal use)				
Very poor	**Poor**	**Neither**	**Good**	**Very good**

Checklist Part II

CAS No:
Internal No:

(to be completed if an impact is quantified in monetary terms)

1. Monetary quantification:

What impact areas are quantified	yes	no	Comments/Description	page(s)
Economic				
Social				

	yes	no	n.a.	Comments/Description	page(s)
Is economic (welfare-economic) analysis performed (no=financial; n.a.= not stated)?					
Is a consistent base-year applied					

What is the source of data quantification is based upon?

	yes	no	n.a.	Comments	page(s)
Pre-existing empirical data? Are references cited? Is quality of data addressed? Are underlying assumptions presented?					
Use of pre-existing model? Are references cited? Is quality of model addressed? Are underlying assumptions presented?					
New data collection?					

2. What methods have been used in quantification?

	yes	no	n.a.	Comments	page(s)
Method not stated					
Cost-benefit-analysis (CBA)					
Cost-effectiveness analysis Achieve target at least costs Achieve most units of target at least costs					
Compliance cost assessment Administrative compliance cost assessment Business compliance cost assessment					
General Equilibrium modelling					
Input-output model					
Other types of macro-economic modelling					
Environmental Impact Assessment models					
Micro-simulation models					
Analysis of Risk and Benefit					
Multi Criteria Analysis, Life Cycle Analysis or DPSIR?					
Others? If yes, please state					

Concerning the choice of type of analysis for the economic assessment	yes	no	Comments?	page(s)
Have the choice of method been justified?				

If yes?

Have availability of data been considered?				
Have in-house experience been considered?				
Other? If yes, please state				

3. If Cost-benefit-analysis have been used:

What methods have been used in benefit valuation?

	yes	no	Comments/Description	page(s)
Method not stated				
Benefit-transfer				
Contingent valuation (willingness to pay)				
Damage-cost-method				
Hedonic pricing / travel cost-method				
Other? If yes, please state				
What methods have been used in cost valuation?				

What is the target used as benchmark for CE-analysis?

4. If Cost-effectiveness (CE) analysis have been used:

	yes	no	n.a.	Comments/Description	page(s)
Does this target correspond with target identified under 'objectives'?					

5. For all types of monetary quantification:

What is the geographical scope of the underlying analysis?

	yes	no	n.a.	Comments/Description	page(s)
Case study					
Country/MS study					
Regional study					
Overall EU-study					
Collection of separate studies					
Other? If yes, please state					

	yes	no	n.a.	Comments/Description	page(s)
Have nationally /regionally decomposed values been used?					
Have common European or US values been used (e.g ExternE-estimates)?					
Has extrapolation or generalisation of results (see geographical scope above) been used? From the specific to the general? From the general to the specific?					

What discount rate is used (if used)?

	yes	no	Comments/Description	page(s)
Is multi-criteria analysis used?				

Checklist part III

(to be completed if an impact is quantified)

CAS No:
Internal No:

What impact areas are quantified	yes	no	Comments/Description	page(s)
Economic				
Social				
Environmental other than the risk assessment				

1. Physical quantification:

What (if any) arguments are used for not using monetary quantification?

	yes	no	Comments Description	page(s)
Proportionality?				
Lack of data?				
Difficult?				
Case is obvious (e.g. high benefits, low costs)				
None				
Other? If yes, please state				

What are the types of data quantified?

	yes	no	Comments/Description	page(s)
Quality (or Disability) Adjusted Life Years				
Employment effects (numbers / percentages)				
Risks (likelihoods)				
Economic indicators				
Distance to political target				
Other? If yes, please state				

What source is the data quantification based upon?

	yes	no	n.a.	Comments/Description	page(s)
Pre-existing empirical data? Are references cited? Is quality of data addressed? Are underlying assumptions presented?					
Use of pre-existing model Are references cited? Is quality of model addressed? Are underlying assumptions presented?					
New data collection					

What is the geographical scope of the underlying analysis?

	yes	no	n.a.	Comments/Description	page(s)
Case study					
Regional study					
Overall EU-study					
Collection of separate studies					
Others? If yes, please state					

	Yes	no	n.a.	Comments/Description	page(s)
Has extrapolation or generalisation of results (see geographical scope above) been used? From the specific to the general? From the general to the specific?					

	Yes	no	n.a.	Comments/Description	page(s)
Is multi-criteria analysis used?					

Previous reports from IMV

2007

CO_2 reduktionsomkostninger ved biodiesel – Dansk produceret biodiesel på raps. Carlsen, Kirsten; Kjellingbro, Marcus; Mogensen, Martin Frank; Kohl, Morten. January.

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Green roads to growth (conference proceedings). Authors: Abildtrup, Jens; Andersen, Kristoffer S.; Braathen, Nils-Axel; Böhringer, Christoph ; Calow, Peter; Djourdjin, Martha; Dubgaard, Alex; Fagerberg, Jan; Gabr, Hesham Morten; Hoffmann, Anders; Jahn, Karin; Kemp, René; Kola, Jukka; Levinson, Arik; Markandya, Anil; Morthorst, Poul Erik; Nielsen, Uffe; Pfaffenberger, Wolfgang; Pianta, Mario; Reinhard, Stijn; Rennings, Klaus; Rosted, Jørgen; Smith, Stephen; Steward, Fred; Stæhr, Karsten; Vollebergh, Herman R.J.; Wrang, Kasper; Ziegler, Andreas. Editors: Henrik Saxe and Clemen Rasmussen. September.

Kørselsafgifter I København – en samfundsøkonomisk analyse. Wrang, Kasper; Nielsen, Uffe; Kohl, Morten. May.

Kørselsafgifter i København – de trafikale effekter. Rich, Jeppe Husted (DTU); Nielsen, Otto Anker (DTU). May.

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Havbrug – Samfundsøkonomiske fordele og ulemper ved øget produktion af ørred i danske farvande. Kohl, Morten. Februar.

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Motorways versus Nature – A Welfare Economic Valuation of Impacts. Olsen, Søren Boye (KVL); Ladenburg, Jacob (KVL); Petersen, Mads Lyngby (IMV), Lopdrup, Ulrich (IMV), Hansen, Anja Skjoldborg (IMV); Dubgaard, Alex (KVL). December.

Environmental Harmful Subsidies - Linkages between subsidies, the environment and the economy. Kjellingbro, Peter Marcus; Skotte, Maria. September.

Natur, miljø og økonomi. Kapitel 7 i "Natur og Miljø 2005 – Påvirkninger og tilstand", eds. Hanne Bach, Niels Christensen, Henrik Gudmundsson, Trine Susanne Jensen, Bo Normander (DMU). Nielsen, Uffe (IMV); Hansen, Anja Skjoldborg (IMV); Lopdrup, Ulrich (IMV). August.

Looking Beyond Kyoto – Trade-offs and Disagreements in Climate Policy. Wrang, Kasper (IMV); Busk, Rico (IMV); Abildgaard, Jørgen (ECON Analysis); Stowell, Debbie (ECON Analysis). May.

Rethinking the Waste Hierarchy. Rasmussen, Clemen (IMV); Vigsø, Dorte (IMV); Ackerman, Frank (Tufts University); Porter, Richard (University of Michigan); Pearce, David (University College London and Imperial College London); Dijkgraaf, Elbert (Erasmus University, Rotterdam); Vollebergh, Herman (Erasmus University, Rotterdam). March.

2004

A Review of the North Atlantic Circulation, Marine Climate Change and its Impact on North European Climate. Olsen, Steffen M. (DMI); Buch, Erik (DMI); Busk, Rico (IMV). May.

Økologi og Økonomi – Fordele og omkostninger ved økologisk fødevareproduktion. Wrang, Kasper; Hansen, Anja Skjoldborg; Egense, Andreas. May.

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2003

Forsigtighedsprincippet i praksis – Konkrete anvendelser af forsigtighedsprincippet i Danmark. Hansen, Anja Skjoldborg; Busk, Rico; Larsen, Thommy. December.

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Litteraturstudie af de samfundsøkonomiske værdier af fordelene ved et renere vandmiljø – Baggrundsnotat til Viden, værdier og valg – Debatoplæg om mål og midler for Vandmiljøplan III. Skotte, Maria. November.

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Viden, værdier og valg. Debatoplæg om mål og midler for Vandmiljøplan III. Hansen, Anja Skjoldborg; Furu, Anita; Kjellingbro, Peter Marcus; Skotte, Maria; Vigsø, Dorte. November.

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Reduktion af radon – En samfundsøkonomisk cost-benefit analyse. Petersen, Mads Lyngby; Larsen, Thommy. August.

Globale økonomiske tab ved vejrkatastrofer – Årsager til stigende tabsomkostninger i det 20. århundrede. Busk, Rico; Wrang, Kasper; Strandbjerg Pedersen, Jesper. September.

2002

Nyttigørelse af returpapir – En samfundsøkonomisk analyse. Petersen, Mads Lyngby; Andersen, Henrik Thormod. December.

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Samfundsøkonomisk vurdering af partikelfiltre – En cost-benefit analyse af partikelfiltre på dieselkøretøjer. Larsen, Thommy; Kristoffersen, Anders; Andersen, Henrik Thormod. November.

Tillægsnotat til rapporten "Pant på engangsemballage". Vigsø, Dorte; Højgaard, Betina.

Pant på engangsemballage? – En samfundsøkonomisk analyse af pantordningen for engangsemballage til øl og sodavand. Vigsø, Dorte; Andersen, Henrik Thormod. October.

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About the report

The new EU Directive on Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) steps into force June 1. 2007. As a new dimension, decisions on authorisations or restrictions can now be informed by socio-economic assessments. This report should be seen as a constructive input to how such analysis can be applied in practice under REACH.

This report reviews previous experiences of socio-economic analyses in connection with regulation of chemical substances. In this report, we analyse a sample of 22 Risk Reduction Strategies conducted under previous EU legislation and six reports conducted by the US Environmental Protection Agency under similar US regulation. Our findings indicate that there is a strong need for improved access to data, more focus on calculation of benefits, systematic coverage of impacts, and more focus on limitations and uncertainties.

About IMV (Environmental Assessment Institute)

IMV is a policy analysis institute. The Institute's approach is to apply socio-economic analyses to environmental issues. Forming critical, independent views on the basis of existing knowledge and communicating these to policy makers and the public is the core objective of the Institute.

IMV was established in 2002. On 1 July 2007 the Institute merges with the secretariat of The Danish Economic Council which in the future will also provide for the new Danish Environmental Economics Council. The merger is expected to strengthen socio-economic analyses of environmental issues in both a national and an international perspective.

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