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Series on Risk Management No. 11

GUIDANCE FOR CONDUCTING RETROSPECTIVE STUDIES ON SOCIO-ECONOMIC ANALYSIS

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OECD Environmental Health and Safety Publications

Series on Risk Management

No. 11

GUIDANCE FOR CONDUCTING RETROSPECTIVE STUDIES ON SOCIO-ECONOMIC ANALYSIS

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among

UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 1999

Other Environmental Health and Safety publications related to risk management include:

Risk Reduction Monograph No. 1: Lead. Background and National Experience with Reducing Risk (1993)

Risk Reduction Monograph No. 2: Methylene Chloride. Background and National Experience with Reducing Risk (1994)

Risk Reduction Monograph No. 3: Selected Brominated Flame Retardants. Background and National Experience with Reducing Risk (1994)

Risk Reduction Monograph No. 4: Mercury. Background and National Experience with Reducing Risk (1994)

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Risk Management Series No. 12: Lead Risk Management Activities in OECD Countries from 1993 to *1998* (in preparation)

Risk Management Series No. 13: Framework for Integrating Socio-Economic Analysis in Chemical Risk Management Decision Making (in preparation)

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 29 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonize policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups made up of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The work of the OECD related to risk management is carried out by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, with Secretariat support from the Environmental Health and Safety Division of the Environment Directorate. As part of its work on risk management, the OECD has issued "status report" monographs on five substances that were, or continue to be, the subject of review: **lead**, **cadmium**, **mercury**, **selected brominated flame retardants** and **methylene chloride**. It has also published two volumes of the **proceedings of the OECD Cadmium Workshop** held in Saltsjöbaden, Sweden, in 1995 and a **survey report on methylene chloride**, supplementing the information presented in the Risk Reduction Monograph on methylene chloride (see list of publications on page 4). In 1996, OECD Environment Ministers endorsed a **Declaration on Risk Reduction for Lead** to advance national and co-operative efforts to reduce the risks from lead exposure.

The Environmental Health and Safety Division publishes documents in several different series, including: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides**; **Risk Management**; **Harmonization of Regulatory Oversight in Biotechnology**; **PRTRs (Pollutant Release and Transfer Registers)**; and **Chemical Accidents**. More information about the Environmental Health and Safety Programme and EHS publications is available on the OECD's web site (see next page).

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO, UNITAR and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

This document contains guidance on how "retrospective" studies of a socio-economic analysis (SEA), conducted in support of a chemical risk management decision, can be carried out. That is, the guidance is intended for those who have already conducted an SEA and implemented risk management measures, and who wish to determine, for example, whether *ex post* impacts match the *ex ante* predictions made in the SEA, and how important key assumptions affecting the analysis were to the decision and to the actual outcomes of the decision.

This is one of three documents being developed by the OECD under its work on socio-economic analysis. The other two – a "framework" document on how to integrate socio-economic analysis into chemical risk management, and a technical guidance document on conducting an SEA – are currently under development.

ACKNOWLEDGEMENTS

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This document was developed under the management of the OECD Issue Team on Socio-Economic Analysis, which comprises representatives of OECD governments, industry, academia and the OECD Secretariat (both the Environmental Health and Safety Division and the Economics Division of the Environment Directorate).

The OECD would like to thank those individuals who provided extensive material and participated in thorough reviews of drafts of this report, including Dr. John Graham of the Harvard Center for Risk Analysis, Arthur Sheffield and Jean-Willy Ileka of Environment Canada, Robert Lee of the United States Environmental Protection Agency, Guy Thiran of ICME, Elin Eysenbach of Procter and Gamble, and the Chemical Manufacturers Association. Thanks are also extended to Klaus Berend of the European Commission for his early guidance on the content of this report.

TABLE OF CONTENTS

LIST OF ACRONYMS

CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CIA	Chemical Industries Association (UK)
DETR	Department of the Environment, Transport and the Regions (UK)
DTI	Department of Trade and Industry (UK)
EIA	Environmental impact assessment
HSE	Health and Safety Executive (UK)
ICME	International Council on Metals and the Environment
MAFF	Ministry of Agriculture, Fisheries and Food (UK)
PPA	Post-project assessment
RFF	Resources for the Future, Inc
RIA	Regulatory impact analysis
RPA	Risk and Policy Analysts Limited
SEA	Socio-economic analysis
UNECE	United Nations Economic Commission for Europe
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
USGAO	United States General Accounting Office
USOMB	United States Office of Management and Budget
VOC	Volatile organic compound

EXECUTIVE SUMMARY

Environmental policies, such as those for chemical risk management, can give rise to a range of different impacts. These include the direct costs to a particular industry sector, or to a number of sectors, of complying with these policies; impacts on suppliers of the affected industry sectors; increased costs to consumers; and wider impacts on the economy. Benefits include improvements in environmental quality, or a reduction in risks to human health. On balance, the benefits of a policy should justify the costs of its implementation.

One of the tools most commonly used in determining whether a risk management measure is justified is socio-economic analysis (SEA). Although approaches to SEA vary among OECD countries, there is broad agreement on the need for a systematic approach to decision-making which makes explicit the implications of a particular risk management action.

The form an SEA takes may vary considerably across appraisals, with some SEAs relying on qualitative information and others on detailed quantitative data, including the valuation of all impacts on industry, consumers, the environment and human health. Given the variation in practice that exists among Member countries, questions are often asked about the degree to which one form of appraisal is better than another, how reliable such appraisals are, and the role they play in decision-making.

Valuable information can be gained on these and related questions by undertaking a retrospective study of the SEA. This involves examining how the SEA was carried out, how well the *ex post* impacts (i.e. the impacts of the measure in practice) correspond to the *ex ante* predictions made in the SEA, and how important key assumptions affecting the analysis were to the decision and to the actual outcomes of the decision. Not only can such retrospective studies offer valuable insights into appraisals already made, but they also provide critical guidance for the conduct of future appraisals.

Currently there is no standard methodology for conducting retrospective studies of SEAs, and appropriate guidance is limited. The aim of this study, therefore, has been to develop guidance on how retrospective studies may be carried out in order to gain the greatest benefits for the future development of socio-economic analysis. The report provides tools to enable decision-makers to determine the scope of a retrospective study, and guidance on appropriate methodologies, drawing on advice issued by government agencies and other commentators. Guidance is also provided on ways the information gained from retrospective studies can be used to improve SEAs' accuracy and usefulness.

The conclusions of this work could feed into other OECD work in this area, such as the development of general guidance on undertaking SEAs (i.e. OECD's work on a "framework" document and a technical guidance document for conducting SEAs in the context of chemical risk management). Ultimately, the guidance provided here should be useful if a series of retrospective studies were commissioned under the auspices of the OECD or by a Member country.

1. Introduction

1.1 OECD risk management activities

OECD's work related to chemical risk management began in 1990, when the Council of the OECD adopted a Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/Final]. This OECD Council Act is aimed at the reduction of risks from chemicals to the environment, and/or to the health of the general public or workers. It is based on the premise that international co-operation in risk reduction activities can enhance the technical and institutional aspects of risk management in Member countries through burden-sharing and a reduction of duplicative efforts. Furthermore, such activities can lead to more effective use of the knowledge of risks being generated through, for example, national chemical reviews and assessments; the OECD co-operative investigation of existing chemicals; and the work of other international organisations conducting hazard and risk evaluations.

The initial work of OECD's Risk Management Programme focused on five chemicals (or groups of chemicals): *lead, mercury, cadmium, brominated flame retardants, and methylene chloride*. For each, a "Risk Reduction Monograph" was published which described the commercial and environmental life cycle of the substance(s), international and national positions concerning risk to man and the environment, and measures taken by OECD countries to reduce such risks. Based on this material, various actions were initiated within the OECD, ranging from the collection of additional information on some chemicals, to overseeing voluntary industry initiatives to reduce certain risks, to a declaration by Member governments that they would advance national and co-operative efforts to reduce other risks.

In 1995, the Joint Meeting of the OECD's Chemicals Group and the Working Party on Chemicals, Pesticides and Biotechnology agreed to review the Risk Management Programme in the light of technological advances and lessons learnt since the Programme was launched in 1990. It was decided that the Programme should focus on two areas: (1) developing methods and technical tools that can be used by OECD and Member countries to enhance their current risk management programmes; and (2) identifying chemical exposures of concern in Member countries and evaluating possible risk management opportunities.

Work on methodologies began in 1996 with the OECD Workshop on Non-Regulatory Initiatives hosted by the United States (Crystal City, Virginia; 10-12 September). This workshop (1) provided a forum for governments, industry and non-governmental organisations to share experiences with non-regulatory initiatives, and (2) provided guidance to the OECD Risk Management Programme on the value and promise of non-regulatory measures.

The results from this workshop provided the foundation for the new Risk Management Programme of Work, which relies, to a considerable degree, on identifying and applying new, innovative and effective techniques for managing risk.

1.2 The project on socio-economic analysis

The Risk Management Programme of Work calls for the initiation of activities to provide guidance to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology and others on the use of cost-benefit analysis and any other techniques that can aid decision-making in risk management. Experience and expertise should be

drawn from work being developed at the national, regional and international levels, and elsewhere within the OECD, to develop useful tools to aid decision-making. Consideration could also be given to how communication of risks can make the cost-benefit analysis more transparent and provide a cost-effective alternative to regulatory approaches for reducing risks.

To meet that charge, an OECD Workshop was held in London (7-9 January 1999) on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision-making. The purpose of this workshop was to:

- provide basic information on the general techniques, approaches and terminology used in the development and application of socio-economic analysis (i.e. describing what exists and how it is used);

- share experiences and identify expertise; identify effective techniques and approaches; and highlight any problems encountered and consider solutions. This would include discussions on: when such an analysis might be appropriate (e.g. in a national, regional or international context); where barriers to its wider use exist and how they may be overcome; and what approaches have been used for valuing costs and benefits; and

- identify areas that need further work within the OECD and Member countries and the means for carrying such work forward.

Participants in this workshop concluded that socio-economic analysis should be a component in both the early and later stages of risk management decision-making for chemicals, and that the OECD should take a leading role in developing, promoting, and assisting in implementing socio-economic analysis on a global scale. The participants also made a number of recommendations, all of which were later endorsed by the OECD's Joint Meeting of the Chemicals Group and Working Party on Chemicals, Pesticides and Biotechnology.

Most importantly, participants recommended that, to carry forward the conclusions of the workshop, a "framework document" should be developed by the OECD which would describe how to integrate socio-economic analysis in chemical risk management decision-making, and also that the OECD should provide guidance on how to conduct studies of SEAs. This would help countries determine under what circumstances socio-economic analysis influenced chemical risk management decisions, and would help identify when such analyses could provide added value to decision-making. In addition, it would help determine under what circumstances there tends to be either an underestimation or overestimation of costs and benefits. The "framework" document, and technical guidance on how to develop SEAs and integrate them in chemical risk management, are currently being prepared. This document has been developed to provide guidance on conducting retrospective studies.

1.3 Background to the study

Environmental policies, such as those for chemical risk management, can give rise to a range of different impacts. These include the direct costs to a particular industry sector or to a number of sectors of complying with the policy, impacts on suppliers of the affected industry sectors, increases in costs to consumers, and wider impacts on the economy. Benefits include improvements in environmental quality or a reduction in risks to human health. On balance, the benefits of a policy should justify the costs of its implementation.

One of the tools most commonly used in determining whether or not a risk management measure is justified is socio-economic analysis (SEA). Although approaches to SEA vary among OECD countries, there is broad agreement on the need for a systematic approach to decision-making which makes explicit the implications of a particular risk management action.

The form an SEA takes may vary considerably across appraisals, with some SEAs relying on qualitative information and others on detailed quantitative data, including the valuation of all impacts on industry, consumers, the environment and human health. Given the variation in practices among Member countries, questions are often asked about the degree to which one form of appraisal is better than another, how reliable such appraisals are, and what role they really do play in decision-making.

Valuable information can be gained on these and related questions by undertaking a retrospective study of the SEA itself. This involves examining how the SEA was carried out, how well the *ex post* impacts (i.e. impacts of the measure in practice) correspond to the *ex ante* predictions of impacts made in the SEA, and how important key assumptions affecting the analysis were to the decision and to the actual outcomes of the decision. Not only can such retrospective studies offer valuable insights into the appraisals already conducted, but they also provide critical guidance for the conduct of future appraisals.

1.4 Aims of the study

Currently there is no standard methodology for conducting retrospective studies of SEAs. Appropriate guidance – for example, the *Treasury Guide for Managers* in the UK (HM Treasury, 1988) – is limited. The aim of this study, therefore, has been to develop guidance on how retrospective studies may be carried out, in order to gain the greatest benefits for the future development of SEA. The conclusions can also feed into other OECD work in this area, such as the development of framework and technical guidance documents. Ultimately, the guidance provided here can be used should a series of retrospective studies be commissioned under the auspices of the OECD or by a Member country.

1.5 Scope and organisation of the report

This report provides guidance that could enable decision-makers to determine the scope of a retrospective study, as well as guidance on appropriate methodologies, drawing on advice issued by government agencies and other commentators. Guidance is also given on ways information obtained through retrospective studies can be used to improve SAEs' accuracy and usefulness.

The reasons for carrying out a retrospective study, and the benefits that can be gained, are set out in Section 2. In Section 3 the distinction is made between retrospective studies of an SEA's **conduct**, i.e. the extent to which it followed appropriate guidance, and those of its **impact**, which examine its influence on decision-makers. Retrospective studies of the SEA's **accuracy** in predicting the outcomes of a decision are addressed in Section 4. Section 5 presents the report's summary and conclusions. Bibliographical references are listed in Section 6. There is a review of previously undertaken retrospective studies in Annex 1.

2. The Purpose and Scope of Retrospective Documents

2.1 The purpose of retrospective studies

The primary purpose of conducting retrospective studies is to assist with the development and improvement of SEAs, responding to questions such as:

- Is one form of SEA more appropriate than another?
- How reliable are the results of SEAs? and
- What role do they play in decision-making?

Without access to the information provided by retrospective studies, there is little factual basis for the development of guidance on the conduct of SEAs, or for making recommendations concerning process or detailed practice. Therefore, retrospective studies could have a major role to play in improving the value to decision-making of socio-economic analysis.

In the context of environmental impact assessment (EIA), Sadler (1988) notes that "a lack of follow-up after a project has been a major constraint on the advancement of EIA practice...It means that there is no opportunity to learn from and utilise the results of case experience." On this basis, "an investment in retrospective research can repay major dividends." This applies equally to retrospective studies of SEAs.

The benefits of conducting a retrospective study therefore include:

- providing feedback on the conduct of SEAs and helping to encourage consistency;

- providing an opportunity to learn from past experience and to apply the lessons learnt to future analyses;

- identifying areas requiring further research or development, for example by highlighting types and categories of impacts that tend to be predicted less accurately; and

- stimulating improvement in, and refinement of, analytical techniques.

Although there are relatively few examples of published retrospective studies (see Annex 1), some common themes are apparent from those studies which have been carried out. For example:

- The failure to explicitly quantify all impacts can result in inefficient use of national resources. This has been highlighted, in particular, by consideration of the cost-effectiveness of health and safety legislation in the United States, although it is more than likely that similar conclusions would be drawn for other countries whose appraisals have failed to quantify such effects;

- There can be significant differences between predicted and actual costs. Some of the data indicate that cost estimates may, for example, be incorrect by as much as 50% owing to changes in technological development, to "strategic bidding" by those with an interest in encouraging or discouraging regulations, or to organisations and individuals not responding to new regulations in the ways predicted;

- Prediction, quantification and valuation of benefits can be even more problematic, as in many cases the data required on dose-response functions, exposure rates and stock/population at risk

required for quantification are unavailable. A second key issue in this regard is the failure of analysts to examine the level of uncertainty surrounding benefit estimates;

- Regardless of the detail and reliability of the SEA, decision-makers may still over-ride the conclusions of the analysis owing to political and other constraints; and

- The failure to involve stakeholders from the beginning can lead to significant problems later on in the decision-making process. However, there are also a number of other issues surrounding such involvement (for example, data collection and acceptability) that need to be considered within the overall SEA process adopted.

Retrospective studies have also highlighted the overall value of socio-economic analysis to the decision-making process. Morgenstern and Landy (1997) conclude that SEAs can contribute significantly to reducing the overall costs of risk management measures and increasing the benefits. They note that "whilst it is not feasible to develop systematic estimates of the dollar values of either these increases in benefits or decreases in costs, in a number of cases the improvements were quite sizeable, amounting to a third or more of the benefits or costs of the rule."

Despite the value of retrospective studies, their more widespread use may be inhibited by budgetary and other constraints, such as the difficulty of obtaining the information needed to estimate the actual impacts that occurred as a consequence of a regulatory action. Yet if the outputs of such studies do result in positive impacts for future risk management measures, the cost of a retrospective study should be more than justified, particularly as many decisions concerning chemical risk management may involve significant economic impacts.

Because of the potential resource requirements of retrospective studies, they are likely to be carried out only for a sample of SEAs. Box 2.1 lists a number of factors to be considered in addressing whether a retrospective study is likely to be useful.

2.2 Types of retrospective studies

Tree types of retrospective studies have been identified. Although not mutually exclusive, each has a different focus:

- **Conduct** studies focus on the way the SEA was carried out, in particular whether appropriate guidance or generally accepted practices were followed, and whether improvements could be made;

- **Impact** studies focus on whether the SEA's results were used in decision-making. In this type of analysis, the aim is to identify reasons why an SEA was or was not influential; and

- **Accuracy** studies focus on whether the analysis predicted the outcomes of a decision in terms of accuracy, calibration and resolution[1] by comparing predicted versus actual impacts. The reasons for any differences are then assessed.

[1] "Accuracy" refers to how well an SEA's predictions correspond to the actual impacts; "calibration" to how well any identified bounds correspond to the actual impacts; and "resolution" to the uncertainty of the values being examined (see Section 4.1.1). The authors thank Dr John Graham of the Harvard Center for Risk Analysis for his help in making this distinction.

In practice, accuracy studies are generally combined with, or preceded by, conduct and/or impact studies, as the way an SEA was conducted is clearly a key factor in the accuracy of its predictions. Indeed, the output of a conduct study will help determine whether an accuracy study is justified. Figure 2.1 is a flowchart for retrospective studies based on these types. It provides the overall framework for the guidance presented later in this report.

Box 2.1 Selection of SEAs for a retrospective study

Consider the following questions (questions 1-5 relate to the original SEA and 6-9 relate to the retrospective study):

1. Was the issue viewed as being of great significance?
For example, was the policy controversial, was media attention high, did the policy result in a large reduction in risk or protection of vulnerable environmental assets, and were the costs of compliance significant?

2. Was the SEA critical to the decision?
For example, was the primary driver the SEA, and was the decision based solely on its results? Or did other factors drive the end decision?

3. Was there a low level of consensus?
For example, consider the degree to which opinions differed between the public, decision makers and those impacted by the policy.

4. Was the input from stakeholders limited?
For example, consider the degree to which stakeholders were involved in consultation and the type of stakeholders involved.

5. Was peer review omitted?
If there was no peer review, had it been considered? If so, why was it rejected?

6. Do suitable and detailed data exist to carry out the study?
For example, will it be relatively straightforward to acquire *ex post* data? If not, will the cost of obtaining such data be prohibitive?

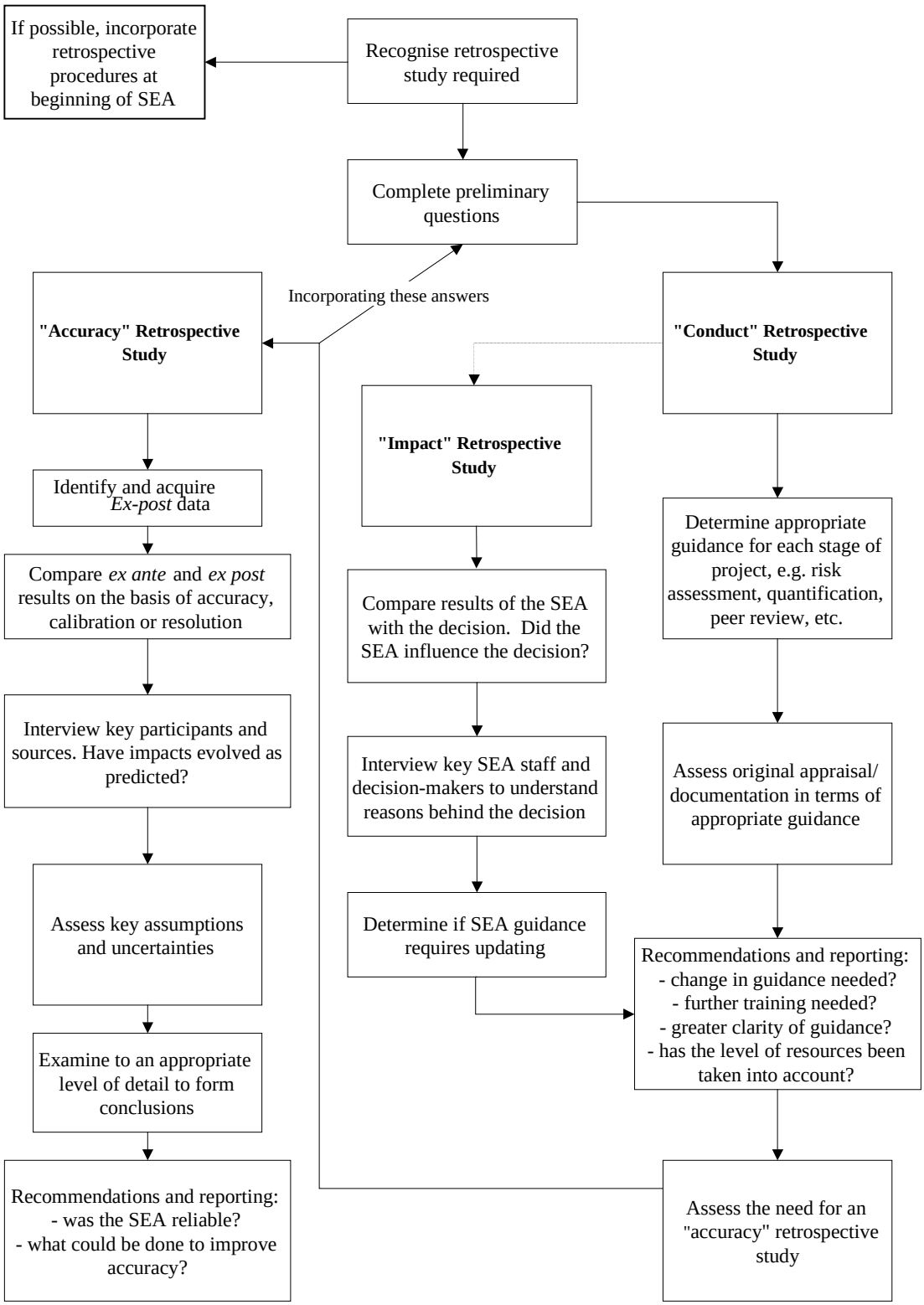
7. Will key parties be willing to co-operate?
For example, will the key parties that have been previously contacted (and that supplied data) be willing to help?

8. Is there sufficient time for a detailed analysis?
A more detailed analysis will take time; the urgency with which the results are required should be taken into account.

9. Are funds available for a detailed analysis?
As with question 8, the longer the study, the greater the funds that may be expended.

If there tend to be more "**yes**" than "**no**" answers, a retrospective study may be useful.

Figure 2.1: Retrospective study guidance



2.3 Selecting the type of study

A range of factors will affect selection of the type of retrospective study to be carried out. Different types of study are likely to have different resource requirements (in both cost and time) and provide different types of information. Conduct or impact studies are likely to be less resource intensive than an accuracy study, as they are unlikely to require the collection of additional data. However, the conduct or impact studies will not be able to identify whether the results of an SEA were accurate, or to determine whether one form of SEA is more appropriate than another.

Clearly, the costs of a retrospective study must be justified by the benefits which are likely to accrue in terms of the improved conduct or accuracy of SEAs. Planning SEAs with the potential for a retrospective study in mind may in itself reduce the costs. In particular, if those conducting the SEA keep clear records of the basis for decisions taken, sources of information, etc., then a retrospective study will be simpler to carry out.

The structure of this approach assumes that once the decision has been made to undertake a retrospective study, a conduct study will usually be done first. This process aids in understanding the basis of the analysis, making it more straightforward to identify reasons for accuracy or inaccuracy.

The decision to undertake an accuracy study would normally be taken after the completion of a conduct or impact study. However, it may be the case that, following implementation of a policy, the appraisal has clearly been so inaccurate that an accuracy study is deemed necessary from the beginning.

2.4 Planning the study

2.4.1 Overview

Guidance developed in the context of EIA post-project analyses emphasises the importance of careful planning to gain the greatest benefits from retrospective studies. Based on the analysis of 11 case studies, the UNECE (1990) notes that good planning not only makes a retrospective study run smoothly but also prevents wastage of funds. For example, changes to the study after it has started may slow down the process and cost money. Factors to be considered in planning the study include the following:

- **purpose** of the study – which should be clearly defined at the outset;
- **timescale** – how long after the original SEA a retrospective study should be carried out;
- **scope** –whether the study should cover a single SEA or a number of them, to detect trends and/or recurring difficulties;
- **roles and responsibilities** of participants (i.e. those carrying out the study, the SEA analysts, the regulatory agency, decision-makers, etc.) – which includes the allocation of costs, research, analysis and management roles;

- **management** – how the study should be managed in terms of stakeholder involvement, requirement for an advisory board, etc.; and

- **reporting** – what form the output of the study will take and how it will be reported.

These issues are considered in more detail in the following sections.

2.4.2 The purpose and timing of retrospective studies

Conduct studies can be carried out any time after completion of an SEA. Indeed, a peer review stage constitutes one form of conduct study. It is also likely that the government agency or other body which commissioned the SEA will have procedures to ensure that SEAs which have been carried out meet their terms of reference and follow any specified guidance. The timing of wider-ranging conduct studies, which review a number of SEAs, may be determined either by planned changes to SEA guidance or as part of a budgetary review process.

Impact studies can be completed only once decision-makers either have taken account of the recommendations of an SEA or have not done so. After this decision has been made, analysts can report on the reasons behind it.

Accuracy studies will generally be conducted after the implementation of the risk management measure, allowing enough time for its effects to be felt. It is important to note that the timescales over which impacts are to be realised may differ, with some direct costs being felt immediately, whilst environmental and health benefits may accrue only over long periods (for example, the effects on the ozone layer of reducing chlorofluorocarbon emissions; see Graham and Hartwell, 1997).

In some cases, accuracy studies may need to be undertaken earlier than is ideal: for example, where changes are planned to the regulation which was the subject of the SEA (as in the case of the UK Packaging Regulations in 1997; see DETR, 1998). In this case, only preliminary evidence is likely to be available as the basis for the study, and data on costs are likely to be more available than data on benefits. Such factors will need to be made clear when reporting the results of the accuracy study.

2.4.3 The scope of retrospective studies

A key question for the scope of conduct studies is whether they should focus on a single SEA or a range of them. Reviews may be carried out separately on individual SEAs, to determine whether they have proved efficient and effective. By contrast, studies of multiple SEAs aim to draw more general lessons about whether appropriate practice has been followed and whether guidance needs to be amended. The scope of a conduct study will be determined primarily by the nature of the guidance which forms the basis for the SEA.

Impact studies may address one regulation at a time, in order to focus on the details behind decision-makers' actions. However, there may also be benefits in reviewing a range of SEAs to determine patterns in the extent to which they influence decisions, and to identify any barriers to effective use of SEAs in decision-making.

It will also be useful for the results of an accuracy study to be considered in the context of reviews of other SEAs involving similar risk management measures. This will highlight any recurring problems and/or trends that restrict SEAs' accuracy and usefulness.

For the long-term development of SEAs, it is important that retrospective studies not only focus on the problems and deficiencies encountered, but also highlight instances where a solution was found, so that the final outcome was not affected. These examples will provide valuable information for others conducting SEAs and for those preparing guidance on SEA processes and practices.

2.4.4 Roles and responsibilities of participants

A number of participants may be involved in a retrospective study, ranging from the analysts who carried out the SEA, and the agency which commissioned it, to government audit and oversight departments, politicians, those affected by the risk management measure which was the subject of the SEA, independent researchers and experts, environmental organisations and the general public. Effective planning of a retrospective study requires that the roles and responsibilities of all such parties are clarified from the outset.

Roles and responsibilities in regard to retrospective studies will be governed by a range of factors, including who has responsibility for conducting SEAs and for developing guidance on them, who controls potential budgets for retrospective studies, any legal requirements for oversight of economic studies, and the degree of external interest in SEAs and hence in retrospective studies. Whatever the basis for conducting a retrospective study, allocation of roles and responsibilities needs to take account of the following factors:

- **Availability of expertise**: Those conducting the study must have sufficient understanding of the SEA process to carry out an effective evaluation. Greater expertise is likely to be required for accuracy than for conduct or impact studies;

- **Access to information**: Involving external parties in the study may assist with access to information on *ex post* impacts, which is particularly important in accuracy studies. Similarly, the co-operation of the analysts who carried out the SEA will be important in understanding the background to the SEA;

- **Impartiality**: Those involved in the SEA may be more willing to discuss any shortcomings and problems with a study team that is seen as "neutral";

- **Learning**: Use of external experts may assist the study team to draw on experience with other SEAs; and

- **Cost**: Using in-house rather than external resources may be more cost-effective. Given the comments reported in the literature on cost as a barrier to carrying out retrospective studies (see Annex 1), this may be a key factor.

2.4.5 Management of the study

Guidance on EIA post-project studies (UNECE, 1990) has stressed the value of advisory bodies in guiding the study process. These are envisaged as boards bringing together industry, government, technical experts and the public. As well as assisting in managing the study, such boards can provide access to information and ensure stakeholder participation.

The applicability of this approach to retrospective studies of SEAs will depend upon their scope and purpose. If the issues covered by an SEA subject to an accuracy study are sensitive, it may be

helpful to involve the public and manage the retrospective study through an advisory board. However, for a conduct or impact study, the costs and time impacts of involving external parties may outweigh the benefits.

2.4.6 Reporting

The purpose and scope of a retrospective study will also affect the way the study findings are reported and disseminated. To fully realise the benefits of such studies, it is important that information that could improve the conduct or accuracy of SEAs is disseminated as widely as possible.

As Annex 1 indicates, relatively few examples of published retrospective studies exist and they are mainly confined to the US. These studies are readily available to the public and to those responsible for carrying out SEAs. In most cases, clear conclusions are drawn and recommendations are made on the value of SEA and on ways the process could be improved.

A larger number of retrospective studies may have been carried out but not reported; if so, it is likely that not all the potential benefits of these studies are being realised. Nevertheless, if the findings of retrospective studies are available to those responsible for commissioning and conducting SEAs, or for preparing guidance on them, at least some value will be generated.

3. Retrospective Studies of Conduct and Impact

3.1 Setting objectives and scope

The broad approach recommended for retrospective studies of the conduct and impact of SEAs is similar. The general steps to be taken are described below, with reference mainly to conduct studies. The specific requirements of impact studies are addressed in more detail in Section 3.4.

The first step in carrying out a conduct or impact analysis is to determine the objectives and scope of the study. As noted in Section 2, the primary objective of a conduct study is to determine whether appropriate guidance was followed in conducting the analysis and, if not, why not. For an impact study, the objective is to identify whether the SEA contributed to the decision and, if not, what prevented it from doing so.

The scope of a conduct study can vary. For example, in some cases only the economic analysis is assessed in terms of compliance with guidance. In other cases, the study may examine the components that make up the whole process (risk assessment, peer review, reporting, decision-making). Of course, the level of detail of each study will be case-specific depending on its purpose. This may range from an initial review by the commissioner of the SEA (usually a government department) through to a detailed examination by independent auditors or external experts.

The greatest value from these studies is likely to arise where a range of analyses is considered, so that common problems and solutions can be identified (bearing in mind the adequacy of resources, as discussed above). Indeed, reviewing a single SEA in isolation may lead to difficulties, as this may fail to identify whether divergences from the guidance are due to shortcomings in the guidance itself which may require modification.

It should be borne in mind that the conduct of an SEA may be significantly affected by the adequacy of the resources available for the study. For example, it may not have been possible to follow guidance in full because of the SEA's limited timescale and budget. In this case, the authors should note the limitations and their potential impacts on the study findings. Comparison across a group of SEAs may be misleading unless the relative resources available are taken into account.

Conduct and impact studies may, of course, identify examples where the analysis is found to be severely flawed, or where decision-makers appear to have made a questionable decision. Concern about the potential for such findings may affect the willingness of analysts and decision-makers to participate in a retrospective study. In general, though, a conduct study is of greater benefit when the aim is to learn from the whole appraisal process rather than to evaluate the performance of individuals or groups.

In our review of published conduct studies, as summarised in Annex 1, the areas covered include:

- Were the most important alternatives considered?
- Were the impacts of these alternatives fully analysed?
- Was information about the analysis, including underlying uncertainties, fully discussed?
- Was the impact of the measure compared against a valid baseline?
- Have the objectives of the SEA been achieved?

- Are the objectives still relevant? and
- Are there any lessons to be learnt?

3.2 Identifying appropriate guidance

The second step in a conduct study is identifying the appropriate guidance against which the SEA will be evaluated. In many OECD countries, statutory or formal government guidance on conducting an SEA (and the components that feed into the process) is already in place. Ideally, to aid both the SEA and any retrospective study, those responsible for commissioning SEAs should specify appropriate guidance to be followed in the terms of reference.

Each stage of the analysis may need to be examined against separate guidance, i.e. the economic appraisal against economic appraisal guidance and the risk assessment against risk assessment guidance. If no guidance exists for a particular aspect of the SEA, it may be necessary to use expert opinion to determine if the appraisal meets accepted techniques throughout the field. Such expert opinion, perhaps in the form of a review group, may add value even where guidance is in place. However, this approach, which may increase the cost of the conduct study, should be used only where justified by the significance of the SEA.

Even where no appropriate guidance is laid down, the approach may have been agreed between the commissioning department and the analyst prior to undertaking the SEA. Where this has not been done, the person undertaking the conduct study may need to consult with the analysts who carried out the original SEA to confirm the approach they adopted. This can add to the time and costs of the retrospective study.

Guidance on the conduct of SEAs may be updated on a regular basis. Where this is done, the SEA should of course be compared with the guidance that was available at the time it was conducted. It may then be useful to carry out a quick further comparison against current guidance, to determine whether any issues identified have been addressed.

To illustrate how the nature of guidance will influence the detailed conduct of a retrospective study, examples are given in Tables 3.1, 3.2 and 3.3 of the questions a study would consider in relation to SEA guidance in Canada, the US and the EU.

3.3 Carrying out the review

3.3.1 Examining the documentation

The conduct study approach begins with an examination of the key documents associated with the SEA. This includes not only the SEA report, but also documents showing why decisions about the form and conduct of the SEA were taken, together with documents relating to other aspects of the study (e.g. the risk assessment). The sources of such documentation will include those responsible for commissioning an SEA, usually a government department, and the analyst who undertook it.

The full range of documentation may, however, not be available in all cases. For example, our review has found that analysts undertaking SEAs did not always document why alternatives were not discussed or considered. In this case, interviews with the key parties may be helpful to supplement document review.

Table 3.1 Canada: regulatory process management standards	
Guidance requirement	**Questions to address in a conduct study**
Consider whether intervention is required at all	Were alternatives to regulation considered? Was the base case examined to determine impacts on health and the environment without intervention?
Determine whether the benefits outweigh the costs	Were all potential benefits and costs identified and assessed?
If the benefits do not exceed the costs, provide supplementary justification for the action	Was justification for the action provided?
Analysis may be qualitative or quantitative	Were the reasons for selection of the approach provided? Were the uncertainties from the analysis addressed?
The SEA should present all relevant information, both qualitative and quantitative, to Ministers and the public	What steps were taken to ensure that all relevant information has been presented? Was information provided to the public as well as Ministers?
A summary of the SEA should be provided to Ministers prior to regulatory approval	Was the SEA completed in line with the timetable for regulatory approval? Was the summary presented to Ministers in sufficient time for their consideration and in a form which aided decision-making?

Table 3.2 US Office of Management and Budget regulatory principles	
Guidance requirement	**Questions to address in a conduct study**
Consideration of degree and nature of risks	Were the risk assessment outputs useful for the SEA? Was due consideration given to the risks of substitutes? Were uncertainties taken into account?
Determination that a regulation is most appropriate	Was a range of regulatory and non-regulatory options considered? Was a baseline included? Was the baseline suitable and realistic?
Full assessment of costs and benefits	Were all costs and benefits identified and assessed? Were uncertainties discussed? Was the assessment of costs and benefits transparent? Were the results presented clearly?
Quantification as far as possible	Were costs and benefits quantified? Was the quantification in monetary terms? If quantification was not in monetary terms, what other measures were used? Was sensitivity analysis undertaken?
Regulations are designed to be cost-effective	Was the most cost-effective option chosen? On what basis was the most cost-effective option chosen?
Determination that the regulation is the least burdensome that could be placed on society	Was a full range of options considered? Could other options be used to achieve similar results at lower cost? Were the impacts to all areas of society considered?

Table 3.3 European Union risk management guidance	
Guidance requirement	**Questions to address in a conduct study**
Clear identification of the risks	Was the risk assessment clear about what the risks might be? Were the risks of potential substitutes considered? Were the uncertainties discussed?
Identification of options for risk reduction	Was a wide range of options considered? Was a baseline included? Was the baseline suitable and realistic?
Consider the effectiveness, practicality, economic impact and monitorability of options	Were the four criteria examined for each option?
Due consideration of costs and benefits	Were costs and benefits considered to the appropriate level for the option? Were any uncertainties highlighted in each case?
Quantification to an appropriate level depending on risks/options considered	Was quantification undertaken? If so, was it to the appropriate level, given the magnitude of impacts, for the risk reduction measures? If quantification was not undertaken, on what basis was the comparison made? Were uncertainties discussed?
The use of monetisation as appropriate	Were costs and benefits expressed in monetary terms? Was monetisation appropriate to the risk reduction option? Was sensitivity analysis undertaken?

3.3.2 Conducting interviews

Although interviews potentially add to the cost and timescale of a retrospective study, they can have significant benefits:

- They provide an additional source of information on how the review was conducted, particularly where documentation of the SEA process is incomplete; and

- They give greater insight into reasons why appropriate guidance was or was not followed, and into constraints and problems faced in the SEA.

The extent to which interviews are undertaken will depend upon the scope of the retrospective study and the extent and completeness of documentation of the SEA. The greatest benefits are likely to be obtained where interviews are designed to address particular gaps in, or questions raised by, the document review.

Depending on the purpose of interviews, it may be appropriate to conduct them with:

- those responsible for commissioning the SEA, to address scope, budget and management issues;

- the analysts who carried out the SEA, for information on detailed conduct of the analysis, problems and difficulties encountered, and ways these were overcome; and

- decision-makers, to understand how and why the SEA was used or not used in the decision (see Section 3.4).

3.3.3 Comparison with appropriate guidance

The aim of a retrospective study should be to focus on areas of significant divergence from appropriate guidance, rather than minor defects in the SEA. Depending upon the nature of the appropriate guidance, this may include the following:

- use of a baseline;
- consideration of a range of options;
- sources of information used;
- treatment of alternatives;
- impact assessment (including quantification and monetisation);
- key assumptions;
- treatment of uncertainty;
- use of sensitivity analysis;
- extent of consultation and stakeholder involvement;
- methods of reporting; and
- whether and how peer review was undertaken.

A good example of the way a conduct study can identify areas of significant divergence from appropriate guidance is given in USGAO (1998). The findings of this report are summarised in Box 3.1. The results give rise to the types of questions that should be considered following an analysis. For example:

- Why did the analysis fail to consider alternatives?
- Why was the range of values used for a statistical life so great, and were such differences justified on risk grounds (e.g. differences in the nature of the risks)?
- Why were executive summaries omitted? and/or
- Why was peer review not carried out in every case?

Determining the answers to such questions is the next step in carrying out a conduct study.

3.3.4 Reasons for divergence from appropriate guidance

By identifying reasons why analysts diverged from appropriate guidance, a retrospective study can determine how appropriate guidance can be improved and/or what other steps should be taken to improve SEA practice.

Reasons for divergence from appropriate guidance can range from a lack of understanding of the guidance to budgetary and time constraints. For example, in the USGAO report one reason for the lack of peer reviews of SEAs was that a number of officials mistakenly identified the publication of proposed or final regulations in the *Federal Register* as a form of external peer review. Others stated that submitting an SEA for peer review would lead to delays and increased costs without adding value.

Time and cost constraints may often be cited as a reason for failure to follow appropriate guidance, and clearly a longer time period and higher budget are likely to allow greater scope for data-gathering and addressing uncertainties. It is therefore likely that an SEA conducted on a

tight budget and a short timescale will be less comprehensive than a costly and lengthy study, although this in itself is not a reason for failure to follow appropriate guidance. Indeed, low-cost studies may be more explicit in describing assumptions contained within the analysis than high-cost studies. On the other hand, studies without significant time and cost constraints which do not follow appropriate guidance merit further investigation.

3.4 The impact of an SEA

The use of SEA findings in decision-making is a complex area. As Morgenstern and Landy (1997) note, it is often difficult to determine whether the SEA or other factors influenced particular aspects of a decision.

The first step in assessing the impact of an SEA is to compare its findings with the outcome of the decision-making process. This will be most straightforward where the SEA has made clear recommendations in favour of a particular risk management measure or group of measures. Where the recommendations are less clear, or where no recommendation is made, further investigation will be needed in the form of interviews with the analysts and/or decision-makers.

Box 3.1 USGAO conduct study of economically significant rules

In March 1998, the US General Accounting Office (USGAO) issued a report that examined all economically significant proposed and final rules issued between July 1996 and March 1997 that covered environment, health and safety. The following is a brief summary of the findings:

- In 15 out of 20 analyses, alternatives were considered to varying degrees;
- All 20 analyses included baseline information;
- All 20 analyses estimated benefits in some terms, and 14 assigned monetary values to these benefits;
- Discount rates used varied from 2.1 to 10%;
- The value of a statistical life ranged from $1.6m to 5.5m (also see Box 4.4);
- Seven out of 15 analyses that addressed uncertainty undertook some form of sensitivity analysis;
- In only one case was it disclosed why appropriate guidance was omitted;
- Out of 20 analyses, 12 contained a clear and concise executive summary;
- Only one of the 20 analyses was submitted for peer review; and
- The primary use of ten of the 20 analyses was to identify the most cost-effective approach.

Source: USGAO (1998).

Such interviews will also be the most effective source of information on why an SEA was or was not influential. Clearly, the views of analysts and decision-makers on this matter may differ. It is important that an impact study aims to take as unbiased a view as possible of the reasons behind the SEA's influence. Interviews with decision-makers can focus on the factors which make an SEA a useful input to their decision process, whilst interviews with analysts may highlight problems they faced in framing their analysis to meet the needs of decision-makers. Only by understanding both views can useful lessons be learnt for the future development of SEAs.

Our review of published retrospective studies identified examples where SEA findings appeared to have little or no influence on the decision. Morgenstern and Landy (1997) identify a number of potential reasons for this, including:

- conflicting regulatory requirements, for example where regulation mandates any action which is proven to reduce risks to health;

- timing problems, for example where the SEA was not completed before the decision needed to be taken;

- a high degree of uncertainty in the analysis, or little difference between the costs and benefits of alternative options; and

- management problems, for example where an SEA was commissioned too late in the decision-making process after options had been rejected for other reasons, or at too junior a level in the agency concerned to adequately influence the decision.

A recent study (RPA, 1998) for the European Commission on the use of SEA by different EU government departments found that such analyses are often introduced rather late in the decision-making process – after alternative options have been identified, but before the preferred option is chosen. This implies that economic analysis is often not being used in the selection of options, and that the outputs of tools such as risk assessment may not be meeting the needs of analysts preparing SEAs. As a result, such analyses may not be contributing fully to decision-making. This conclusion is also borne out in part by the above study, which found that in some countries SEAs may only affect the end choice of action "sometimes" or "rarely". Even recognising that SEAs are just one input to the decision-making process, it suggests that there is room for improving their effectiveness.

By contrast, other studies have found that nearly all the analyses reviewed contributed to the decision-making process, though they rarely led decision-makers to select different alternatives or to fundamentally revise the regulatory proposal under consideration. In the USGAO report, for example, officials with decision-making responsibility were interviewed to obtain detailed explanations of how the SEA findings were used (USGAO, 1998). Their responses included:

- identifying the most cost-effective approach;
- implementing health-based regulations cost-effectively;
- defending/documenting a regulatory decision; and
- reducing health risks at feasible costs.

The failure of an SEA to contribute to decision-making can have significant implications for the benefits of the SEA process. Although the reasons for this failure may include, for example, a lack of significant differences between options in cost-benefit terms, retrospective studies should pay particular attention to understanding such cases.

The study for the European Commission (RPA, 1998) found that there tend to be three key applications for SEAs: general policy appraisal, long-term strategic planning, and standard setting. Most of the countries surveyed used both cost-benefit analysis and cost-effectiveness analysis for general policy appraisal. The findings suggest that, in this area of appraisal, SEAs do contribute to decision-making.

3.5 Reporting and recommendations

3.5.1 Reporting

Reports on retrospective conduct and impact studies should highlight any divergence from the appropriate guidance, as well as lack of influence on the decision subsequently taken and the reasons. Reporting should take account of the potential sensitivities of those responsible for the original SEA and emphasise learning points, rather than criticising individuals or groups (unless there is good reason and/or an appropriate context). It is good practice to ensure that participants in the SEA study have an opportunity to review the report, and to correct any factual errors, before it is published.

The nature of the report will depend upon how widely it is to be distributed and its target audience. As a general guide, the following elements are recommended:

- an executive summary;
- an introductory section providing background to the study and the approach adopted for the retrospective analysis;
- a summary of the original SEA, together with its assumptions and results;
- details regarding the appropriate guidance used (there may be several for the different aspects of the SEA);
- a comparison between appropriate guidance and the original SEA;
- a determination and explanation of any divergence from appropriate guidance, and of the implications of this divergence;
- details regarding the impact of the SEA on decision-makers; and
- conclusions and recommendations.

Reports should be clear and concise, and written with the relevant audience in mind. Over-emphasis on detailed technical matters can cloud the focus and findings if the report is for a non-technical audience.

3.5.2 Recommendations

The recommendations following a conduct study will be driven by the results of the review process. They could include, for example:

- the need for changes to or clarification of guidance;
- the need for greater clarity in the terms of reference and on the part of those commissioning an SEA;
- the need for better training of analysts carrying out SEAs (or decision-makers using SEAs); and

- issues concerning the timing, scope and resources required for SEAs.

Recommendations can be made at many different levels, including those of decision-makers, commissioning departments and analysts. They should therefore be tailored to the audience to which they are addressed. If deemed necessary, the recommendations may be split into sections corresponding to the key stakeholders involved in the SEA process.

3.6 The need for further review

The completion of a conduct or impact study may highlight particular areas where further review might be required. In particular, it provides the opportunity to determine if there is a need for an accuracy study. Three key decision criteria aid in this determination:

- Where appropriate guidance was not followed and the SEA has been judged seriously inadequate, an accuracy study is unlikely to generate further useful information. However, where an SEA complied with appropriate guidance, an accuracy study will provide information on the value of that guidance in predicting outcomes;

- Where an SEA did not influence the decision, it may not be possible to conduct an accuracy study since the measure evaluated by the SEA may not have been implemented. However, where a measure judged by the SEA to be sub-optimal has been implemented, an accuracy study could indicate whether the SEA predictions of the measure's impact were correct; and

- Where the conduct study found that the ability to follow appropriate guidance was constrained, for example by lack of data, an accuracy study could show how critical such constraints were to the SEA overall.

In all cases where a decision is to be made on whether to carry out a more detailed study, the costs of such a study should be outweighed by its benefits (these costs and benefits relate solely to undertaking the accuracy study and not to impacts within the original SEA). Measuring such benefits in these cases is difficult, given that they tend to be qualitative. Ideally, the results should assist all those involved in the SEA process to ensure a closer match between predicted and actual impacts.

These decision criteria should be supplemented with the preliminary questions discussed in Section 2 (as outlined in Figure 2.1), which guide the decision-maker in determining whether an accuracy study may be required. Accuracy studies are discussed in depth in the next section.

4. Accuracy Studies

4.1 Defining the objectives and scope

4.1.1 Setting the objectives

Following completion of the conduct study and a decision on the need for further review, the next stage is to assess the SEA's accuracy in predicting the impacts of risk management measures. In contrast to the "bottom up" and inward-looking approach of a conduct study, an accuracy study takes a "top down" approach, looking at the results of an SEA and then identifying reasons for any inaccuracies. It is also outward-focused, in that it compares the SEA's findings with changes occurring in the real world.

As noted in Section 2.2, the concept of accuracy has three aspects: accuracy, calibration and resolution. "Accuracy" concerns the degree to which the predictions in the original SEA correspond to actual impacts, "calibration" the degree to which these impacts fall within the upper and lower bounds determined by the SEA (where such bounds were identified), and "resolution" the uncertainty associated with the values being examined.

The emphasis of an accuracy study will therefore depend upon the nature of the predictions made in the original SEA and the degree of uncertainty associated with them. Nevertheless, the broad approach to an accuracy study is similar, whatever the emphasis.

The main elements of an accuracy assessment include:

- identification and acquisition of *ex post*[2] data;
- comparison of *ex post* and *ex ante*[3] results;
- discussions with key staff involved in the original analysis and assessment of the analysis's assumptions and uncertainties, to determine the reasons for differences; and
- recommendations and reporting of results.

Each of these elements is described further below.

4.1.2 Establishing the scope

Factors to be considered in establishing the scope of an accuracy study include:

- whether all aspects of the SEA will be studied or only certain areas (for example, information on costs which was critical to the decision); and

- whether the study will cover one SEA or a series (as with conduct studies, covering a range of SEAs may generate more useful recommendations as long as they are comparable).

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[2] The term *ex post* refers to actual impacts occurring in the "real world" after the predictive analysis was conducted.

[3] The term *ex ante* refers to expected impacts derived as part of a predictive analysis.

Although the broad scope of an accuracy study can be agreed at the outset, the level of detail required will become apparent only as the study progresses. For example, a detailed assessment is required only where significant errors or uncertainties are found within the SEA. Any issues, or areas of potential inaccuracy, highlighted by the conduct assessment should automatically be flagged for inclusion in the accuracy assessment. As more information is gathered as part of the accuracy assessment, additional errors or uncertainties may be discovered that require further investigation.

As noted earlier, the accuracy study should identify problems that were addressed and solved by the analysts, along with uncertainties that were not addressed in the original SEA. These problems, and their solutions, can provide valuable lessons and guidance for analysts coping with similar difficulties that may arise in future SEAs.

Where the impacts of regulation were different from those predicted, the reviewer should revisit the assumptions used in the selection of possible impacts and consider the likelihood and effect of alternative impacts. This should help in identifying the reasons behind these differences. An initial "logic check" of the assumptions within the analysis can be undertaken by comparing decision criteria (such as cost-benefit ratios, net present values, cost-effectiveness, and so on) with similar analysis conducted elsewhere.

In addition to comparing the scale of the predicted impacts (i.e. were they as significant/insignificant as expected?), an accuracy study should evaluate whether the impacts occur within the predicted timeframe and location. It is also important to consider impacts arising from the risk management measure which were not predicted by the SEA.

Experience with EIAs has shown that *ex post* comparisons of the impacts of a risk management measure with *ex ante* forecasts can be complicated when (Dipper *et al*, 1998):

- forecasts are imprecise and qualitative;
- post-report changes invalidate the basis on which forecasts were made; and
- monitoring of the impacts of a decision is inadequate.

While the presence of imprecise and qualitative predictions should be identified in the conduct study, it may still be worth proceeding with an accuracy study to determine whether the direction and order of magnitude of impacts were predicted correctly.

4.2 Identifying and acquiring information

To carry out a full accuracy study, considerable detail regarding the *ex post* and *ex ante* impact estimates is required. In only three of the ten cases examined by Morgenstern and Landy (1997) was there sufficient information to judge the accuracy of *ex ante* estimates. This problem may arise, in particular, where the benefits of a risk management measure occur at levels close to the limits of detectability (e.g. where predictions are based on low dose extrapolation).

In such cases it may still be possible to carry out a partial accuracy study, for example by determining whether concentrations or exposures have declined as the result of a risk management measure or by assessing only the accuracy of cost estimates. Such partial accuracy studies may still yield useful information about the ability of socio-economic analysis to predict outcomes. However, they should be used with caution. Accuracy in regard to one aspect of an SEA does not necessarily imply equal levels of accuracy in regard to other aspects.

The first step in identifying and acquiring information for an accuracy study is to identify the key *ex ante* predictions within the SEA and to determine the main sources of information on which these were based. This information can then be used to plan the acquisition of *ex post* data. Potential sources of *ex post* data include, but are not limited to, the following:

- monitoring by government agencies and others of the impacts of policies;
- analysis by industry organisations of the private costs of regulatory changes;
- assessments by NGOs of the effects of regulatory change on the environment;
- academic research; and
- subsequent SEAs carried out on related policy decisions.

Where no such data sources are readily available, there may be a need for the retrospective study to repeat the data-gathering processes that formed the basis for the original SEA. Clearly, such an exercise could be both costly and time-consuming; it is therefore particularly important in such cases that the scope of data-gathering is clearly defined and is focused on the most critical aspects of the SEA.

Obtaining *ex ante* and *ex post* data will be simplified where the analyst conducting the SEA is aware that an accuracy study may be carried out. In this case, the analyst can ensure that the original data are set aside or presented in such a manner that they can be easily identified and assessed in any subsequent study, and that the reasons for any decisions taken on the basis of the analysis are properly recorded. This effort at the start of the regulatory process can save considerable time and money, as well as increase the accuracy and therefore the usefulness of any retrospective study. Once appropriate data have been obtained, the predicted impacts of the regulation can be compared to the actual impacts of the risk management measure.

4.3 Comparing ex post and ex ante results

The aim in comparing *ex post* and *ex ante* results is to identify major discrepancies and the reasons underlying them. An accuracy study should therefore commence by comparing the overall impacts predicted by the SEA with those which actually occurred. Where major differences are found, the study can be extended to cover each stage of the SEA, from the initial risk assessment to quantification of the data, any monetisation of impacts, and the sensitivity analysis that assessed the robustness of the SEA.

In carrying out the comparison, a number of factors should be borne in mind:

- The timescales over which impacts are generated may be different. For example, impacts on human health and the environment can take considerably longer to materialise than private costs to industry;

- Private cost data are more likely to be gathered for other reasons, such as financial accounting, than are data on wider impacts; and

- Whereas private costs to industry can often be objectively measured, other impacts may be more subjective and more difficult to measure (such as those on human health and the environment).

Discrepancies between predicted and actual impacts may result from uncertainties and assumptions in the SEA; consideration of these discrepancies may provide an appropriate point from which to determine the exact cause of the variance between the predicted and actual impact estimates. Box 4.1 highlights some areas of inaccuracy identified in past SEAs.

Box 4.1 Discrepancies in predicted and actual costs of regulation

- MAFF (1996) found that actual costs were, on average, 10% higher than the predicted costs. This was considered to reflect a weakness within the early appraisal stage of underestimating the costs of engineering projects, suggesting that the estimated costs of implementation increase as the projects evolve. Additional areas of concern highlighted in another report on the subject (MAFF, 1997) estimated an average cost variance of 22% between predicted and actual costs. In this case, variance was attributed to failure to consider maintenance and operating costs.

- A retrospective study on an economic appraisal of amendments to the US Clean Air Act calculated the total actual costs of implementation to be between $2 and 4.9 billion by 2010. The predicted costs were calculated to be between $4 and 5 billion. The reasons cited for the variance (particularly of the lower bound) were the introduction of new (and unforeseen) technologies and flexibility in the timing of implementation of the regulation, which spread the costs of compliance over an extended time period (USEPA, 1997).

- An examination of before- and after-the-fact cost estimates for 25 environmental regulations in the US, Canada, Norway and Singapore found that in 12 cases cost estimates made before implementation were higher than actual costs. In six other cases the pre-implementation estimates were too low. Cost overestimation was often due to errors in predicting the extent of the emission reductions that the regulation would trigger. Such errors could also lead to overestimation of a regulation's benefits (Hogue, 1999).

The level of detail of comparison of *ex post* and *ex ante* data should be sufficient to allow the reasons for any discrepancies to be identified. Identification of shortcomings is likely to require discussions with analysts and decision-makers involved in the original SEA, as well as a review of relevant documentation.

Where a retrospective study can compare *ex post* with *ex ante* costs (whether private or related to regulatory enforcement) and discrepancies are identified, it will be possible to determine, for example, what magnitude of difference in benefits would be necessary to justify the original decision in the light of the revised level of costs.

4.4 Identification of reasons for differences

4.4.1 Sources of uncertainty in ex ante *estimates*

The critical stage in an accuracy study is the identification of reasons for differences between predicted and actual impacts. This is the stage which will provide the most valuable information for the development and improvement of the SEA process.

Differences between *ex ante* predictions and *ex post* measurements of impacts have been attributed to a variety of factors, ranging from inadequacies in the initial risk review (or

assessment) to institutional factors (Morgenstern and Landy, 1997). Potential sources of inaccuracy identified in published retrospective studies (see Annex 1) include the following:

- uncertainties over future relative prices of key private cost components;
- uncertainties over technological change and the way affected industries will adapt to a new regulation;
- uncertainties about the wider economic consequences of taking a particular action;
- scientific uncertainties;
- uncertainties regarding the timeframe over which impacts will occur;
- uncertainties as to the most appropriate standard values for use in the analysis, in particular as part of the transference of values from previous studies;
- uncertainties associated with modelling activities, particularly in regard to any assumptions which have to be made by analysts;
- uncertainties concerning related decisions and how they may affect the outcome; and
- uncertainties as to policy goals and how to weigh one decision factor against others.

In an accuracy study, it is important to separate discrepancies arising from lack of data, or incorrect assumptions or models, from errors in transcribing or analysing the original data set used in the SEA. The latter type of error should have been identified as part of a conduct study.

4.4.2 Inaccuracies in impact estimates

The factors leading to inaccuracies may differ depending on the type of impact. For example, inaccuracies in the predicted costs or benefits of risk management measures can be linked to:

- technology forcing (development of more cost-effective approaches in response to regulations);
- strategic bidding (overstatement of potential costs or benefits in order to influence a decision); or
- unpredicted responses (selection of a different mix of approaches in order to conform to a regulation than those assumed for the purposes of the SEA).

The *ex post* data, supplemented by interviews where necessary, should indicate whether any of these factors applies to the SEA being studied.

By contrast, inaccuracies in evaluating health and environmental impacts are more often linked to:

- lack of scientific information on cause-effect relationships;
- poor information on exposure rates;

- insufficient detail on stock/populations exposed; and/or
- incomplete information for the monetary valuation of impacts.

These issues may not be resolved by the time the accuracy study is carried out, thus limiting the extent to which inaccuracies can be identified.

Morgenstern and Landy (1997) identify uncertainties in underlying scientific data as a major cause of inaccuracy in SEAs. Box 4.2 outlines how such uncertainties have affected SEAs in practice.

Box 4.2 Impact of data uncertainties on the SEA process

- The data used to assess the economic costs of a Nepalese soil erosion project failed to include air quality data for some regions of the country, substituting spatially aggregated data where possible. The SEA was also characterised by errors in the air quality model itself (Dixon *et al.*, 1986).

- The lack of quantifiable data to assess the costs and benefits of reducing the lead content in gasoline in the US had an impact on the validity of the evidence supporting the regulation, and opened the SEA to considerable criticism. The study also lacked data supporting the link between lead exposure and adverse human health effects (Nichols, 1997).

- Similar problems arose in an assessment of water quality in the Great Lakes in the US, where the link between adverse human health effects and water quality were not clearly defined or supported by scientific evidence (Castillo *et al.*, 1997).

- The same problems developed again during an SEA of a proposal to reduce the lead content in drinking water. Significant uncertainties arose due to the lack of a clearly defined link between adverse human health effects and lead poisoning from drinking contaminated water (Levin, 1997).

One controversial source of potential error is the monetisation of non-market impacts, particularly those affecting human health and the environment. Such valuations are often based on willingness-to-pay values elicited via survey techniques (such as contingent valuation). Placing a value on non-market goods aims to ensure that resources are allocated in an economically efficient manner (in other words, that their true economic value is taken into account); however, it is criticised by those who argue that such techniques cannot reliably determine how much society is actually willing to pay.

Such valuations do, however, offer a means of including directly incorporating such impacts within the analysis and avoid the danger of excluding them (where a zero value may be attributed by decision-makers) simply because they may not be explicitly valued in the SEA. A detailed discussion of the pros and cons of monetary valuation is outside the scope of this report. Box 4.3 highlights an example where an SEA encountered difficulties placing a monetary value on wildlife and the environment in an economy where no market values or market equivalent existed.

Similar controversy surrounds the valuation of a statistical human life. An example of human life having been monetised, and the associated problems, are described in Box 4.4.

Box 4.3 Monetising environmental values

An example of an SEA that ran into valuation difficulties is an assessment of the costs of conserving the Ordesa and Monte Perdido National Park in Spain, where the lack of a market made the valuation of natural resources difficult (Martinez, 1995). Quantification was undertaken using alternative methods of monetisation based on the value visitors to the park placed on the resource. However, the resulting estimates excluded the benefits and the values of other users and non-users, reducing the validity of the valuation exercise, the SEA, and hence its value to the decision-making process.

Box 4.4 Monetisation of a statistical human life

A review of 20 SEAs by the USGAO (1998) highlighted six analyses that explicitly assigned a monetary value to a human life, given that a reduction in mortality was a benefit associated with the proposed ruling assessed by each SEA. These values ranged from $1.6 to 5.5 million per statistical life. Three of the remaining 14 analyses identified a reduction in risk mortality as a benefit, but did not place a monetary value on it. The USGAO notes that in these cases the regulatory body conducting the SEA did not assign monetary values to a statistical life since it "conveys a false sense of precision and is morally objectionable."

Clearly, it will be difficult for an accuracy study to compare definitively predicted and actual outcomes based on such valuation of environmental and health benefits. It may be possible, however, to compare the magnitude of impacts predicted by an SEA with the likely magnitude of actual impacts, and to determine whether any differences would have had a significant impact on the value attributed to the benefits. Similarly, the values used in the SEA for environmental and health benefits can be compared to values used in other studies to determine whether the adoption of other value estimates would have a significant impact on estimates of potential net benefit. Although this approach cannot determine whether the original valuation method was "wrong" or "right", it can indicate the potential scale of uncertainty associated with the values used.

Of course, care should be taken when utilising the transference of values from one study to another. Not only may this process increase the uncertainty surrounding the analysis, but it may also undermine the validity of the analysis as a whole. A great volume of literature exists on the advantages and disadvantages of transferring values. One of the most recent examples is an examination of mortality with regard to air pollution in the UK by the Interdepartmental Group on Costs and Benefits (1999).

4.4.3 Drawing conclusions

The aim of an accuracy study is to determine which factors are the main source of differences between the effects predicted by an SEA and those realised. This determination will rely on a detailed understanding of the basis of the SEA, which is best obtained through interviews with the analysts. Interviews with other key parties, such as industry representatives or voluntary groups, may provide additional insights into why changes did not occur as predicted, why changes that were not predicted did occur, and whether these were foreseeable by the analysts carrying out the SEA.

In drawing conclusions on the causes of inaccuracy, it is also important to bear in mind the scope, timescale and budget of the SEA. The study should attempt to identify additional stages of analysis which could have addressed the causes of inaccuracy and improved the SEA's overall quality.

To judge the overall influence of any inaccuracies within an SEA, studies would need to answer the question: "If the inaccuracy had been known at the time, would the decision have been different?" As noted in Section 3.3.4, many factors other than the SEA are likely to have played a part in the decision. Nevertheless, by studying the basis of the original decision and interviewing decision-makers, it may be possible to draw tentative conclusions on this point.

If the accuracy study has covered a range of SEAs, conclusions may also be drawn about common factors which affect their accuracy and usefulness. Where the SEAs have used a range of different methodologies, it may also be possible to comment on which methodology is most appropriate in different circumstances, thus helping to answer the question: "Is one form of SEA more appropriate than another?" No examples of retrospective studies addressing this issue have been identified. It may be that such an approach requires a level of sophistication in carrying out retrospective studies which has not yet been reached in practice.

4.5 Recommendations and reporting

The aim of an accuracy study is to present findings and recommendations which will help improve the accuracy and usefulness of future SEAs. As with conduct studies, the form of reporting on an accuracy study will be governed by the scope and objectives of the study and its intended audience. Examples of reporting formats range from summaries of key findings (MAFF, 1997) to detailed descriptions of case studies of SEAs, together with an overview of common issues and problems (Morgenstern and Landy, 1997).

The main issues and any recommendations should be clearly discussed in the report. Transparency is the key in communicating the results of the retrospective study to users, who may include economists in government and industry, decision-makers and the public as well as analysts. Key issues and assumptions, including the scope and objectives of the study, should be clearly presented and described. As with conduct studies, those involved in the SEAs under study should have the opportunity to review the report prior to publication and to correct any factual errors. As with SEAs themselves, it may be useful to submit the accuracy study to some form of peer review.

It may also be useful to present the results of the accuracy assessment in the context of the results of other, similar analyses in order to place the level of accuracy of the SEA(s) studied within the context of other studies (i.e. does this SEA have greater uncertainties or inaccuracies than other SEAs? and, if so, why?). It is also useful to include an executive summary at the start of the reporting document, to aid its transparency.

Recommendations from an accuracy study may include, for example:

- changes to the scope and timing of future SEAs that may be required in order to increase their accuracy and usefulness;

- advice on the circumstances under which SEAs provide the greatest value to the decision-making process;

- ways the accuracy of SEAs could be improved (e.g. methodological changes, data availability); and

- areas for further research and investigation.

The aim of such recommendations should be to assist those involved in SEAs to develop more useful and effective approaches to conducting the required analyses, and hence to increase the value of SEAs to the decision-making process.

5. Summary and Conclusions

5.1 The value of retrospective studies

The aim of carrying out retrospective studies is to assist with the development and improvement of the SEA process by answering questions on the role, conduct, impact and accuracy of SEAs in practice.

The use of SEA in decision-making is increasing. It is becoming mandatory for some types of decisions in certain OECD countries, and can involve considerable time and resources. With access to the information which can be provided by retrospective studies, a factual basis for the development and improvement of guidance on the conduct of SEAs can be established. Resources can be optimised by governments' sharing information, conducting joint retrospective studies, and communicating best practices within the OECD Chemicals Programme.

Our review, summarised in Annex 1, found relatively few examples of published retrospective studies. Budgetary and other constraints, such as difficulties in obtaining adequate data, limit the extent to which such studies can be carried out. However, properly conducted retrospective studies can provide significant advantages for the development of SEA, including:

- providing feedback on the conduct of SEAs and helping to encourage consistency;
- giving an opportunity to learn from past experience and to apply the lessons learnt to future analyses;
- highlighting areas requiring further research or development, for example the types and categories of impacts that tend to be predicted less accurately; and
- stimulating improvement in, and refinement of, analytical techniques.

Other benefits may include the fact that those undertaking SEAs in the future may do so with increased rigour, in the knowledge that a retrospective study may be undertaken. In addition, the evaluation of whether risk management measures are achieving the impacts expected can contribute to overall reviews of risk management programmes.

One factor which may have limited the extent to which retrospective studies have been carried out, and increased their cost and resource requirements, is the lack of a methodology based on common principles. This report sets out initial guidance on conducting retrospective studies in a systematic and cost-effective manner, in order to enable their benefits in the development of SEA to be realised.

5.2 When and how should retrospective studies be carried out?

Guidance is given on when retrospective studies might be conducted and when they are most likely to add value, together with the factors to be considered in deciding to undertake a retrospective study. Advice on determining the scope and methodology for a retrospective study is also provided, drawing from the published examples of such studies and from practice elsewhere, notably post-project analyses of environmental impact assessments.

For the purposes of this guidance, we have identified three types of retrospective study: **conduct**, **impact** and **accuracy** studies. These types of study differ in their emphasis, resource requirements and timing. To ensure a cost-effective approach, the report recommends that in most cases a conduct and/or impact study is undertaken first:

- A conduct study involves identifying relevant appropriate guidance on the conduct of an SEA and then determining, through examination of documents and discussions with those involved in the original analysis, whether appropriate guidance was followed. Where appropriate guidance was not followed, the reasons are determined.

- Conduct studies can generate recommendations for the modification or clarification of appropriate guidance, training of analysts, or the timing, scope and resources required for SEAs. Impact studies extend the analysis to consider use of the SEA by decision-makers. The combination of these two types of study enables the analyst to determine whether an SEA that did not follow guidance did influence the decision, and vice versa.

The completion of a conduct and/or impact study may highlight particular areas where further review might be required. In particular, it provides the opportunity to determine if there is a need for an accuracy study:

- An accuracy study takes a top down approach, looking at the outcome of an SEA and then identifying reasons for any inaccuracies, in contrast to the "bottom up" approach of a conduct and/or impact study. It is also outward-focused, in that it compares the findings of the SEA with changes that actually took place. The main resource requirement and potential area of difficulty for an accuracy study lies in gathering the real-world data needed to make such comparisons.

To improve cost-effectiveness, it is recommended that all three types of study should focus on identifying areas of significant discrepancy and the reasons that underlie them.

5.3 The importance of advance planning

The cost-effectiveness of retrospective studies can be enhanced with the aid of planning and preparation throughout the SEA and retrospective study processes. Where SEAs are carried out in the knowledge that a retrospective study may follow, analysts will be encouraged to keep a full record of decisions made, factors considered and sources of information used. Not only is this good practice for an SEA, it will also provide a firm foundation of data on which a retrospective study can draw. Considerable time and effort can be wasted in retrospective studies where such records are not available.

Experience with post-project analysis in the context of EIA has also demonstrated the importance of careful planning for the retrospective studies themselves. It is important to be clear in advance about, for example, the scope and purpose of the study, the roles and responsibilities of participants, study management, and the form of reporting. Guidance on these matters is given in the preceding sections.

5.4 The contribution of retrospective studies to the development of SEA

To ensure effective planning, those responsible for commissioning and carrying out SEAs need to be convinced of the value of retrospective studies. The small number of retrospective studies

published to date have highlighted the overall value of SEA to the decision-making process. Morgenstern and Landy (1997), for example, conclude that SEAs can contribute significantly to reducing the overall costs of policy measures and increasing their benefits.

Retrospective studies carried out following the guidance set out in this report will provide recommendations on a range of issues, for example:

- the need for changes to or clarification of appropriate guidance;
- the need for greater clarity in the terms of reference and on the part of those commissioning the study;
- the need for better training of analysts carrying out SEAs;
- issues concerning the timing, scope and resources required for SEAs;
- changes to the scope and timing of future SEAs which may be required in order to increase their accuracy and usefulness;
- advice on the circumstances under which SEAs provide the greatest value to the decision-making process;
- ways the accuracy of SEAs could be improved (e.g. methodological changes, data availability); and
- areas for further research and investigation.

Such recommendations could make a significant contribution to the development of the SEA process. In addition, retrospective studies on a wide range of SEA methodologies, carried out using approaches based on common principles, could provide valuable guidance on the most appropriate methodologies to use under different circumstances and on the better integration of SEA into the overall risk management process. In the meantime, however, more work is warranted to truly test the effectiveness of retrospective studies.

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Annex 1

Review of Retrospective Studies

A.1 Availability of retrospective studies

To identify examples of retrospective studies of SEAs that focused on policies (such as the introduction of restrictions on a hazardous substance), we have undertaken both consultation with key organisations/individuals and an extensive literature review. We have identified a number of retrospective studies, the majority of which are based on experience in the United States. In other countries, retrospective studies appear to have been carried out for limited ranges of activities and tend to focus more on projects than policies (such as capital expenditure on the construction of flood defences).

We found examples of all three types of retrospective study ("conduct", "impact" and "accuracy"), with several studies addressing all three aspects to some extent. Most studies, though, looked in broad terms at the approach taken in the SEA, the analytical problems encountered, and the extent to which the predicted impacts actually occurred.

A.2 SEAs referred to in this annex

Table A.1 lists the SEAs covered by the retrospective studies and other sources referred to in this report, together with a brief description of their context.

A.3 The conduct of SEAs

Overview

Although concluding overall that the value of SEAs outweighs their costs, Morgenstern and Landy (1997) identify a range of factors which limited the usefulness of SEAs in contributing to decision-making by increasing the uncertainty of the analysis. Their findings are generally supported by the retrospective studies, with a number of studies containing criticisms of methods of undertaking SEAs, including:

- lack of consideration of alternative regulatory options;
- lack of consideration of all categories of costs and benefits;
- failure to adequately discuss the uncertainties of their analyses;
- presentation of a single estimate of costs and benefits, rather than a range of values that would reflect potential uncertainties;
- use of unrealistic assumptions in preparing exposure estimates;
- not assigning monetary values to health benefits;
- not considering distributional effects;
- not adequately considering the impact of the regulation on employment; and
- not including overall economic trends in the analyses.

In a review of all 61 RIAs carried out by the USEPA between 1990 and mid-1995, Hahn (1996) observes "wide variation from very poor to very good" in the technical quality of analyses. However, Morgenstern and Landy (1997), commenting on a sample of analyses which admittedly was not selected to be representative, conclude that "*per se* [the] economic analyses are fundamentally sound" with no gross errors such as double counting, confusion of costs and benefits, equating of transfer payments with economic costs or benefits, or failure to discount. They further conclude that "the studies are generally credible."

Many criticisms of SEAs relate to the availability of underlying data for the analysis (Box A.1).

Table A.1 SEAs covered by retrospective studies referred to in this report*

Regulation of interest	**Description**
Prioritising environmental improvement measures, 1997 (*Wit* et al., *1997)*	ICI Holland commissioned researchers to develop a quantitative method for prioritising environmental improvement investment. This involved quantification and monetisation of the costs and environmental effects of each measure and ranking on the basis of cost-effectiveness.
Lead in gasoline, 1985 (*Nichols, 1997*)	The USEPA promulgated a rule to cut the use of lead in gasoline by over an order of magnitude in less than a year. This decision was supported by an extensive CBA. The Regulatory Impact Analysis (RIA) prepared by USEPA estimated that the benefits outweighed costs by roughly three-to-one.
OCPSF industry effluent regulations, 1987 (*Caulkins and Sessions, 1997*)	In November 1987, the USEPA promulgated final effluent guideline regulations for the organic chemical, plastics and synthetic fibres (OCPSF) industry. The RIA had three main components: a direct cost analysis, an employment and industry impact analysis, and a water-related benefits analysis.
Montreal Protocol on Substances that Deplete the Ozone Layer (*Hammitt, 1997*)	Reviews of the scientific, analytical and regulatory issues surrounding US adoption of the agreement.
Asbestos, 1979-89 (*Augustyniak, 1997)*	From 1979 to 1989, the USEPA dedicated $7 million to conducting analyses of the costs and benefits of banning asbestos from around 30 product categories.
Lead contamination of drinking water, 1991 (*Levin, 1997*)	On June 7, 1991, the USEPA published a regulation to control lead contamination of drinking water. Adoption of this rule was largely due to the economic analysis reflected in the 1991 lead in drinking water RIA (which projected annual net benefits of more than $3.3 billion).
Use and disposal of sewage sludge, 1993 (*Podar* et al., *1997*)	On February 19, 1993, the USEPA published its final regulation on the use and disposal of sewage sludge. The RIA accompanying the proposed regulation assessed the costs and some of the benefits of four alternative regulatory options.
Great Lakes Water Quality Guidance (*Castillo* et al., *1997*)	In 1990, the Clean Water Act was amended to require that USEPA promulgate the Great Lakes Water Quality Guidance for all eight states and create a level playing field among them. The benefits and costs of EPA's guidance were evaluated in an RIA completed in early 1995.
Management of toxic substances, particularly PERC, 1996 (*Sheffield A* et al *(1998)*	CBA was used to evaluate four options for the management of toxic substances, particularly perchloroethylene (PERC), which is used in dry cleaning. The results of the assessment suggested that benefits exceeded the costs for all four options, and that due to competitiveness within the industry the costs of compliance were likely to be absorbed by individual companies.

Regulation of interest	**Description**
Cost of regulation in setting an environmental standard (*Karmokolias, 1996*)	This analysis assessed the costs of pollution abatement using data from the source supported by the results of other studies. The costs and benefits of the major environmental impacts were not included due to expense, lack of available data and concern that the findings might support a case for retroactive compensation. Inclusion of these costs would have enhanced the credibility of the results and increased the usefulness of the analysis to local managers and regulators.
Chemical industry environmental investment costs, 1992-96 (*Chemical Industries Assoc., 1997*)	The UK Chemical Industries Association monitored chemical company environmental investment intentions and actual investment for a period of four years following introduction of major new environmental regulatory requirements.
Conservation of the Monte Perdido National Park, 1993/94 (*Martinez, 1995*)	A study in 1995 assessing the costs of conserving the Ordesa and Monte Perdido National Park in Spain concluded that the investment to guarantee the conservation of the national park was justified; however, the result should be treated with caution.
Numerous life-saving interventions (*Tengs* et al., *1995*)	A study in the US examined 200 programmes designed to benefit human health. Of these 200, both cost-effective and cost-ineffective programmes were implemented. The study calculated that reducing the number of cost-ineffective programmes implemented would save an estimated 60,000 lives per year at no increased cost to taxpayers or industry.
Standards for regulating used oil, 1984 (*USEPA, 1987*)	A 1987 study by USEPA on means of defining standards for regulating used oil showed that regulation would reduce costs and increase the level of recycling, thereby decreasing risk. The benefits were not monetised by this assessment, instead being represented by reductions in potential cancer risks. Uncertainties were seen to exist in the analysis, and the recommendation was that the results are viewed in comparison with the results of other studies.
PCB transformers, 1982 (*USEPA, 1987*)	The USEPA completed three CBA studies in conjunction with the regulation of PCBs, although only one of these analyses was associated with a "major" rule. The CBA was used to verify the economic effectiveness of the proposed regulation, and was useful in presenting alternative solutions for each section of the industry.
Testing new pesticide formulations, 1981 (*USEPA, 1987*)	An analysis of the costs and benefits of testing new pesticide formulations indicated considerable expense with no significant benefits. Because this regulatory option was not proven to be cost-effective, it was removed from the decision-making process. Assessment of alternative options highlighted the most cost-effective options, which were then selected for use in the regulation.

Regulation of interest	Description
Effluent guidelines for organic chemicals, plastic resins and synthetic fibres, 1983 (*USEPA, 1987)*	The effluent guidelines for organic chemicals, plastic resins and synthetic fibres have been assessed by USEPA based on available technology. The resulting guidelines were developed on the basis of health and ecological effects, economic benefits and costs, and available technology.
Reduction of coke emissions released during the production of steel, 1982 (*USEPA, 1987*)	The USEPA wanted to reduce coke emissions released during the production of steel by 90% by 1998. Although the result was not a particularly cost-effective outcome, Congress had not given permission for the USEPA to base the final ruling on cost-benefit considerations, and so the analysis had little influence on the final outcome.
Emissions of nitrogen dioxide, 1984 (*USEPA, 1987*)	Five regulatory options were considered as potential means of regulating emissions of nitrogen dioxide. The benefits were not monetised, and were instead represented by the reduced emissions that occur under different standards for nitrogen dioxide. Costs were calculated. It was concluded that there were no significant costs associated with the introduction of the standard, and that no plant closings would occur as a result of the regulation.
Concentration of particulate matter, 1984 (*USEPA, 1987*)	The USEPA used existing data to estimate the benefits of reducing atmospheric concentrations of particulate matter. There was no recognised impact on small businesses, nor was a major change in industry structure predicted.
VOC emissions control, 1996 *(ENDS Report, 1996)*	The UK Department of Trade and Industry commissioned consultants to review the costs and benefits of proposals to tighten controls over VOC emissions. The consultants encountered a number of problems with data availability, limiting the extent to which a fully quantified SEA could be prepared.
Nepal Hill Forest Development Project, 1983 (*Dixon* et al., *1986*)	A 1996 proposal to reduce soil erosion and increase land productivity in the forests of Nepal concluded that the benefits of the programme were considered to equal the difference in land values (i.e. the economic value of the products of the land) with and without the proposed programme. The analysis was not considered accurately quantifiable and was therefore not included in the decision-making process.
* Full references can be found in Section 6 of this report.	

Consideration of alternative options

Socio-economic analysis of proposed regulations can provide both the regulator and those affected by regulations with the necessary information to make a decision on whether the regulation should proceed. SEAs are commonly used to defend or support regulatory decisions; their use for other decision-making purposes is very limited.

Morgenstern and Landy (1997) indicate that, when carried out in relation to regulatory decision-making, SEAs should allow comparison of policy goals as well as a means to achieve those

goals. In practice, however, they identify a tendency to limit the policy options addressed in an SEA, leading to the exclusion of important alternatives.

In a review of 20 SEAs (USGAO, 1998), the US Office of Management and Budget (OMB) found that all but five had included consideration of alternative regulatory options. In some cases, however, discussion of the alternatives was minimal, with no explanation provided for the limited, or lack of, consideration of alternatives.

The OMB cited budgetary and time constraints as the main reasons given for lack of consideration of alternatives in SEAs. Morgenstern and Landy (1997), however, do not agree that this is the only reason. They note that the explanation probably lies in a variety of institutional factors, for example the fact that SEAs are often initiated by junior staff with limited input from more senior or experienced managers or from external organisations, and that SEAs are initiated too late in the decision-making process, when some options have already been discounted and a preferred option may have been developed.

This finding is supported by a review of practice within EU countries (RPA, 1998), which found that most government departments introduce the use of CEA or CBA after alternative options have already been identified. SEA is therefore not being used to assist in the selection of options, but only to assist in identifying or assessing the implications of a preferred option.

Box A.1 Review of proposals to tighten controls on VOC emissions

The UK Department of Trade and Industry commissioned consultants to review the costs and benefits of proposals to tighten controls on VOC emissions. The consultants encountered a number of problems with data availability limiting the extent to which a fully quantified SEA could be prepared:

- The consultants were unable to put money values on the benefits of reduced ozone pollution due to "insufficient information on the valuation of health benefits";
- The focus of the analysis was on end-of-pipe abatement methods rather than on substitution options. The consultants were unable to predict the number of affected companies which would select each option; and
- No attempt was made to quantify the business benefits of reducing VOC emissions, for example from improved product quality and reduced waste, which had been demonstrated in "best practice" case studies.

Source: ENDS Report (1996).

Stakeholder involvement

In a number of countries, stakeholder involvement in the development of environmental regulations is either mandatory or common practice. The UK Royal Commission on Environmental Pollution (RCEP, 1998) notes that, based on the experience of decision-makers and other experts, "consultation has an important role to play in publicising proposals, stimulating debate, and eliciting a broad range of comments on the practicability and desirability of proposals." This should be undertaken as early as possible in the appraisal process; indeed, it is stated that "the public should be involved in the formulation of strategies, rather than merely

being consulted on already drafted proposals." To achieve this, government departments should (RCEP, 1998):

- consider how the new methods of stakeholder involvement should be incorporated into the procedures for considering environmental issues and setting environmental standards, including the framing of questions to be addressed in the analysis and communication of the results of scientific assessments in a comprehensive form; and

- collate the experience gained, and draw up guidelines for use of the new methods designed both to maximise their effectiveness and preserve their integrity.

The type of approach espoused by RCEP is applied in Canada (RPA, 1998). Stakeholder involvement in economic appraisals is required by the Regulatory Policy of 1995, which states that all regulatory authorities must "ensure that Canadians are consulted, and that they have an opportunity to participate in developing or modifying regulations and regulatory programs." The effectiveness of this policy, and the performance of regulatory authorities in relation to it, is monitored by the Treasury Board Secretariat. On a separate level, Health Canada and Environment Canada allow for extensive stakeholder involvement within the Options Evaluation Process. This consultative process, which is used in the development of regulations specific to CEPA toxic chemicals, lists public participation as one of its key principles. Industry, aboriginal groups and non-governmental organisations are the key stakeholders included in the Options Evaluation Process.

The timing of ministries' opening policy up to scrutiny from stakeholders is a critical factor in determining whether stakeholders can actually get involved in the appraisal process, and to what extent. While some departments involve stakeholders throughout the policy development process, where this includes the analytical phase, in other departments the time available for input is more limited. This can cause problems for stakeholders, as many interest groups meet irregularly and may not have teams in place capable of reviewing an analysis before the required date.

The UK Ministry of Agriculture, Fisheries and Food (MAFF, 1996) found that, in the coastal and flood defence projects analysed, consultation with environmental bodies was on the whole timely and comprehensive. In addition, the evaluation applauded the standard of consultation undertaken in the period of designing scheme proposals. However, there have also been some problems (Box A.2).

Box A.2 Problems with stakeholder involvement experienced by MAFF

- The flood banks alongside a river were due to be raised. Consultees failed to understand that the bank would be raised to such a level that the view of the river from the ground floor of properties would be obscured. In the end, the banks were lowered by 600 mm to partially restore the view.

- Despite prior consultation, problems were encountered following construction of a small rural flood defence scheme – a new channel being constructed alongside the road. After construction, there was an outcry that the channel resembled a motorway. After detailed discussions, the channel was covered and grassed over (in effect, becoming a culvert) and a crash barrier was replaced with bollards.

Source: MAFF (1996).

This experience shows that early consultations between the promoting authorities and conservation and other public bodies is beneficial (and may provide additional benefits to the local community). It was found that good public consultation contributes significantly to the successful completion of schemes. This is particularly true when it is undertaken well in advance of the schemes' design/construction.

Morgenstern and Landy (1997), however, have found that in most cases the USEPA relied exclusively on internal experts to decide on the analysis to be conducted and the options to be considered. Generally, it is only once a regulation is formally proposed that it can be examined by the public. Morgenstern and Landy comment that, whilst this may have administrative advantages, it fails to tap in at the early stages to the considerable knowledge base that exists in the private sector and the NGO community. This might enable policy-makers to address some of the shortcomings in SEAs identified in retrospective studies.

Inadequacies in the risk assessment

Because SEA relies on the availability of large amounts of data, gaps in the data can significantly increase uncertainty within the analysis. Morgenstern and Landy (1997) note that "economic analysis of the benefits of environmental policies typically depends on the existence of a well-done risk assessment." In general, economic analysis only adds value when scientists have laid the groundwork by developing credible quantitative estimates of the underlying physical relationships.

In practice, the retrospective studies show many gaps in underlying data. Indeed, in the example of water pollution and the organic chemicals industry, Caulkins and Sessions (1997) note that "for nearly all the effluent guidelines there was no attempt other than the environmental analysis to evaluate the benefits to be gained from the regulation. There was no risk analysis, no evaluation of whether the dischargers affected highly valued water bodies, no assessment of impacts on drinking water intakes, and so forth."

Inadequacies in the risk assessment can range from a lack of basic scientific understanding to problems in determining how those affected will respond to a proposed regulation. These difficulties have included identification of changes in air and water quality that result from reduced emissions, problems in identifying strong and credible links between pollutants and disease in humans, and problems in finding data that are relevant to the proposal being assessed. In many cases, the degree of uncertainty can be so high that the results cannot be treated with any great confidence.

Examples of basic scientific data having been lacking include the following:

- In the case of the Nepal soil erosion project (Dixon *et al.*, 1986), uncertainties in the original data included the lack of available air quality data for some regions of the country, potential errors in the air quality models themselves, and the use of spatially aggregated emissions data;

- The assessment of a proposed regulation to improve public health by requiring the removal of 90% of the lead in gasoline, with total removal by 1995, was plagued by criticism of a lack of quantifiable data and the lack of a strong link between the risk of lead exposure and adverse effects on human health (Nichols, 1997); and

- In the case of the Great Lakes Water Quality regulation (Castillo *et al.,* 1997), the USEPA faced problems in addressing health risks. In the past, there had been a concentration on cancer-causing risks. However, in this case the focus was on human non-cancer risks and there were significant data shortages.

A further example of such problems is presented in Box A.3.

Analysts also commonly experienced difficulty in identifying a strong link between the presence of a pollutant in the environment and human exposure to that pollutant leading to health risks. Where a strong link cannot be identified, the regulatory body can have difficulty justifying the proposed regulation, particularly where the regulation is controversial or unpopular.

Box A.3 Uncertainties and data gaps concerning lead in drinking water

A number of uncertainties and data gaps are highlighted in the study on lead in drinking water RIA conducted by the USEPA:

- the lack of complete data, which necessitated assumptions and best engineering judgements about the levels of lead in drinking water and efficacy of corrosion treatment;
- the likelihood of decreasing lead levels in blood or preventing adverse health effects;
- the relationship between lead exposure and cognitive damage, foetal effects or cardiovascular health; and
- the effectiveness of corrosion treatment in reducing corrosion damage.

Source: Levin (1997).

In many cases, the SEA is based on highly risk or scientific aggregated data, which restricts the analyst's detailed understanding of its basis. Often the only available data have not been collected with economic analyses in mind (Box A.4). Generally, the analyst will have little opportunity to collect new risk data for the SEA and will therefore have to make the best use possible of available information. In this case, the analyst should provide an appropriate, transparent discussion of any data limitations and their implications for interpretation of the SEA findings.

Uncertainties may be exacerbated by the approach used by analysts to deal with data gaps (Box A.5) and where the timescale over which the policy will be implemented is long (Box A.6).

Box A.4 Use of scientific data collected for other purposes

- An assessment by the UK Department of the Environment (DoE, 1997) of the costs and benefits of four alternative options for the disposal of marine dredgings used data that were originally intended for scientific monitoring rather than economic use; and

- UK analysts assessing the impact of pollutants on the atmosphere found that the only available health effects data came from the US, where the chemical loading was different from that in the UK. This resulted in dose-effect relationships that might not be fully applicable to the UK situation (Interdepartmental Group on Costs and Benefits, 1999).

Box A.5 Conservative assumptions where data are lacking

One of the problems highlighted by an asbestos RIA conducted by the USEPA regards the conservative assumptions used when data were lacking. A specific example concerns the method of assigning surrogate exposures. This method was not developed until after the proposed rule was issued, and therefore "missing exposure information resulted in treating the case as if exposure, for that product in that circumstance, was zero." This assumption led to an underestimate of the benefits of the rule.

Source: Augustyniak (1997).

Box A.6 Long-term uncertainties regarding CFC emissions

An assessment of the costs and benefits of reducing CFC emissions was required to consider long-term effects. The analyses therefore had to consider a longer time period than is usual for the economic analyses of toxic pollutants. These longer time periods led to uncertainties regarding the method and effect of implementation, as well as the actual number of people (i.e. in view of population growth) that would be affected by CFCs.

Source: Graham and Hartwell (1997).

Problems with the baseline

Morgenstern and Landy (1997) note that the baseline refers to the status of environmental and economic conditions in the absence of planned policy intervention. Determining a baseline is therefore central to the construction of economic analyses. A study of 25 environmental regulations by Resources for the Future (RFF) found that mis-estimation of the baseline can lead to wrong predictions of both the costs and benefits of a regulation (Hogue, 1999).

The retrospective studies reviewed indicate that the issue of the baseline is not always effectively addressed by SEAs. In its report on post-project evaluation, MAFF (1996) found that, in setting the options, 70% of 86 scheme evaluations considered the "do-nothing" option (i.e. a baseline). A year later, MAFF (1997) found that 66% of 79 scheme evaluations considered the "do-nothing" option (i.e. a baseline).

Problems with benefits assessment

The studies reviewed indicate that particular problems had been experienced in quantifying and valuing the benefits of proposed changes. Often studies failed to allocate values to all of the benefits identified (Boxes A.7 and Box A.8).

Similar difficulties arose in the assessment of a proposal to reduce soil erosion and increase land productivity in the forests of Nepal. Although the programme's benefits were considered equivalent to the difference in land values (i.e. the economic value of the products of the land) with and without the proposed programme, the main difficulty was in placing a monetary value on inputs from various land uses. The programme's contribution to the control of soil erosion, landslides and flooding was not accurately quantifiable and was omitted from the assessment.

Box A.7 Incomplete benefits assessment (1)

For a water pollution and organic chemicals industry RIA, the industry-specific benefits analysis attempted to identify all relevant beneficial outcomes. Only a subset of these could be quantified and valued in monetary terms. Water quality benefits were estimated for recreational boating and fishing, commercial fishing and non-use values, whilst air quality benefits were estimated for cancer reduction and smog reduction. Significant impacts not valued in monetary values included:

- reductions in health risks from air emissions of non-carcinogenic pollutants;
- reductions in health risks associated with air emissions of non-priority pollutants;
- reductions in health risks from consumption of contaminated fish or drinking water;
- reductions in health risks to swimmers; and
- ecological benefits.

Source: USEPA (1987).

Box A.8 Incomplete benefits assessment (2)

A study assessing the costs of conserving the Ordesa and Monte Perdido National Park in Spain encountered difficulties in placing a monetary value on investments in natural areas, where the lack of a market which evaluates (in monetary terms) the value placed on the park by users is accounted for by the use of other methods of quantification. The analysis concluded that the investment to guarantee the conservation of the national park was justified. However, because of the difficulties of monetising other use and non-use values, the result should be treated with caution.

Source: Martinez (1995).

In the lead in gasoline case, several benefits could not be quantified due to insufficient data. In addition to these problems, scientific uncertainty and the difficulties of placing a monetary value on human health prevented complete monetisation of the health benefits from lead reduction. The authors of the retrospective study concluded that benefits calculated by the assessment were therefore likely to be significantly underestimated.[1]

Failure to fully quantify benefits does not necessarily negate the findings of an SEA. For example, in the review of nitrogen oxide emissions, the USEPA combined a range of aggregate benefit estimates which were acknowledged as being imprecise due to the omission of the effects of relevant pollutants. The estimates also did not account for the impacts of non-point source pollution. The resulting estimates ranged from $320 million to 4.95 billion. The estimated costs ranged from $46.3 to 48.5 million. All of the benefit estimates contained a large degree of uncertainty. However, the results indicated the benefits of regulation to be significantly greater than the costs.

[1] An external reviewer has noted that this may not be the case. Impacts might not have been quantified because they could be judged of "insufficient importance to influence the overall benefits significantly."

A study undertaken for the European Commission (RPA, 1999a) went so far as to attempt to determine the most comprehensive cost-benefit analysis possible, focusing on three case studies. The findings suggested that many current appraisals only consider a sub-set of the actual effects of any particular policy, excluding such impacts as:

- effects on related markets;
- employment and wider effects (e.g. social effects and income distribution);
- multiplier effects;
- risks from alternative hazardous substances;
- impacts on other receptors (e.g. in the case of air pollution); and
- benefits from secondary savings (such as secondary emission savings).

One approach to filling gaps in benefits data is to use values derived in other circumstances (benefits transfer). This can give rise to problems when the values were developed for different sets of circumstances (Boxes A.9 and A.10).

Because of such problems, there is a tendency for SEAs to focus on risks and costs rather than on benefits. Of the 20 analyses reviewed by the USOMB (USGAO, 1998), 14 described some benefits in monetary values and seven of these described the benefits of the proposed regulation and of an alternative. Six of the 20 analyses calculated net benefits; six did not describe any benefits in monetary terms. Because the reasons for these omissions were not presented in the analyses, the degree of uncertainty inherent in the analyses increased and the clarity with which the analyses were presented decreased.

Box A.9 Problems with benefits transfer (1)

In an SEA of a proposed change to regulations governing landfills, property value studies involving leaking landfills were used as one method of estimating the value of stricter standards for new landfills. Yet many of the original property value studies were unable to distinguish between the general nuisance aspect of a landfill and the fact that it may have produced problem leachates. The analysis was therefore criticised for overstating the benefits of stricter standards.

Source: Morgenstern and Landy (1997).

Box A.10 Problems with benefits transfer (2)

As part of work on the preparation of an SEA of new national air quality objectives, the UK Department of Health convened a group of medical and valuation experts to assist in the monetary valuation of relevant health effects. This group examined the available transfer data and concluded that there was "a lack of direct empirical evidence on the monetary valuation of the reduction in risk of deaths brought forward by air pollution...it is not appropriate to apply empirical evidence on monetary valuation of the reduction in risk of deaths in [road] accidents directly and without adjustment to the air pollution context."* This finding contrasts with work undertaken for the European Commission which applied the unadjusted value of statistical life estimates derived for road accidents to the valuation of air pollution mortalities.**

*Sources: *Interdepartmental Group on Costs and Benefits (1999) and **IVM* et al. *(1997).*

One example of this is the assessment of costs and benefits undertaken by the USEPA in defining standards for regulating used oil, which showed that regulation would reduce costs and increase the level of recycling, thereby decreasing risk. The benefits were not monetised by this assessment, instead being represented by reductions in potential cancer risks. Cost-effectiveness ratios were developed for each alternative by dividing total annual costs by the number of cancer cases avoided.

In their critique of the municipal sludge management RIA, Podar *et al.* (1997) state that "USEPA devoted considerable effort to develop the risk assessments and cost estimates...USEPA did not attempt to monetise cancer and non-cancer benefits, nor to quantify non-health benefits to human welfare or ecological systems." They go on to state that "the agency apparently had little interest in developing, much less using, benefit-cost information as a basis for designing and evaluating its regulatory options with respect to municipal sewage sludge."

Although CBA was not used in its entirety, the USEPA did make use of several "CBA-like" implicit assumptions to guide the regulation towards a point where it focused on protecting health and the environment whilst minimising compliance costs (by using risk assessments and implicit trade-offs between costs and risk reductions, and promoting the beneficial use of sewage sludge). Box A.11 gives a further example of the focus on costs rather than benefits.

Box A.11 Lack of emphasis on benefits valuation

In the Great Lakes water quality case, both time and funding for the RIA were weighted towards the analysis of costs and pollutant-loading reductions relative to the analysis of benefits. The reasoning behind this was two-fold:

1) the limited timeframe within which regulatory decisions are made at the USEPA; and

2) the fact that methodologies for assessing benefits from water quality improvements in monetary terms are not well suited to national regulations, as they tend to be site-specific.

Given this latter point, the USEPA indicates that, looking back on the way the benefits assessment was conducted, original benefits research (such as a survey of anglers) would have been preferable.

Source: Castillo et al. *(1997).*

Dealing with uncertainty

A number of the retrospective studies suggested ways in which uncertainty could be addressed in SEAs. Nichols (1997) highlights two key areas where uncertainty was reduced in the lead in gasoline RIA:

- When exposure estimates based on a large-scale survey were used, not only did this reduce uncertainty, but it also increased credibility; and

- the model used to estimate costs was already developed.

Hence, as Nichols states, these factors "illustrate the value of longer-term research and development efforts to provide the building blocks for analysis."

The majority of analyses reviewed by the USOMB (USGAO, 1998) acknowledged the uncertainties which may arise through the lack of available data, population variability, natural conditions or a lack of technical knowledge. The USOMB notes that uncertainty can be predicted through statistical techniques to test the sensitivity of the analyses. In practice, though, MAFF found that only 36% of analyses in 1996 and 38% in 1997 included sensitivity testing.

Presentation of the SEA

Transparency is essential in communicating the results of the analysis to decision-makers and the public. However, few of the retrospective studies considered the issue of presentation.

A report by the Royal Commission on Environmental Pollution concerning environmental standards (RCEP, 1998) notes that at each stage "the presentation to decision-makers of the results of the analyses...should clearly state the assumptions and limitations of each analysis. It will usually be necessary to offer several options and their implications, so far as these can be gauged." In addition, the RCEP recommended that "there should be an audit trail documenting all the considerations taken into account in reaching a decision and how they were taken into account." It highlighted the fact that the economic appraisal should set out all the major uncertainties and include sensitivity analysis altering key assumptions.

The USOMB review of 20 analyses, however, found that whilst some analyses included summaries which increased clarity, others would have benefited from a peer review to enhance the clarity and credibility of the results.

A.4 The impact of SEAs

Morgenstern and Landy (1997) note that, in reviewing individual policy decisions, it is often difficult to determine whether SEAs or other factors influenced particular aspects of the decision.

The majority of SEAs covered by the retrospective studies were carried out to support regulatory decision-making. Indeed, Nichols (1997) in a study of the SEA on lead in gasoline, commented that "the primary motivation for conducting the Regulatory Impact Assessment is to meet the requirements of executive orders that apply to major rules, not to inform decision-makers." Only a limited number of examples were found where SEAs were carried out to assist business with decision-making (CEC, 1998; Karmokolias, 1996). Box A.12 gives one example of such a study.

Nevertheless, the retrospective studies contained a number of examples where SEAs appeared to have had a clear influence. Equally, there were examples where the SEA findings appeared irrelevant to the decision.

Examples of SEAs influencing regulatory development

Examples of retrospective studies indicating that SEAs played pivotal roles include determining the level of stringency and the implementation schedule in both the lead in drinking water and lead in gasoline rules (Morgenstern and Landy, 1997). Other examples are presented in Boxes A.13 and A.14.

BOX A.12 SEA for investment ranking

A major chemical company based in the Netherlands commissioned researchers to develop a quantitative method for prioritising environmental improvement measures. The aim of the method was to enable the costs and benefits of different improvement measures to be fully quantified and valued in monetary terms. Environmental benefits were specified in terms of environmental "themes", based on the Netherlands National Environmental Policy Plan targets and the company's own method for comparing the "environmental burden" of different pollutants. Values were allocated to the benefits using a shadow pricing methodology.

The company planned to use the methodology to prioritise its environmental investments, and in discussions with regulatory authorities on priorities for action. It was expected to provide a basis for evaluating environmental performance improvements and reporting on progress to stakeholders.

Source: Wit et al. *(1997*).

Box A.13 The role of SEA in battery recycling in North America

RIA was used to assess the costs and benefits of regulatory alternatives for encouraging the recycling of batteries containing secondary lead in North America. The estimated costs and benefits were calculated over an 11-year period using three alternative baselines. All proposed options suggested minimal impacts on small businesses and retail outlets. While occupational exposure decreased, ambient exposure (particularly for children living near a smelter) increased significantly. The outcome of the RIA suggested that although the costs of regulation were minimal, the risks of lead-acid and the costs of policy implementation outweighed the benefits. Therefore, no further action was taken.

Source: Harvard Center for Risk Analysis (1995).

Box A.14 The role of SEA in management of perchloroethylene

CBA was used to evaluate four options for the management of toxic substances, particularly perchloroethylene (PERC), used in the dry cleaning sector. The information was derived from dry cleaners and household expenditures on dry cleaning. Environmental benefits were linked to the avoidance of environmental damage to plants and groundwater from discharges of PERC. The costs of compliance for the dry cleaners were based on the assumption of constant prices and demand for their services, and that dry cleaners would choose the least cost option for compliance. The cost assessment regarding households indicated that people were willing to pay up to 8% more on their dry cleaning bill, although the expected increase was only 3%. The results of the assessment suggested that benefits exceeded the costs for all four options, and that due to competitiveness within the industry the costs of compliance were likely to be absorbed by the individual companies. This case is cited as an example of economics playing a key role in the final determination of viable options that were acceptable to most of the stakeholders.

Source: Sheffield A et al. *(1998)*.

Another example of SEA resulting in the alteration of plans for regulatory change concerns pesticides. An analysis of the costs and benefits of testing new pesticide formulations indicated considerable expense with no significant benefits. Because this regulatory option was not proven to be cost-effective, it was removed from the decision-making process. Assessment of alternative options highlighted the most cost-effective option, which was then selected for use in the regulation. Table A.2 highlights a number of examples where the SEA has led to changes in the regulations.

Table A.2 Changes in regulations brought about by SEA*

Rule	**Improvements leading to increased benefits**	**Improvements leading to decreased costs**
CFCs		Adoption of tradeable CFC consumption permits (within the US); permitting of production trades internationally (allowed by the Montreal Protocol); use of consumption taxes (within the US) to further control CFC use
Great Lakes		Scaling back of numeric criteria; selection of cost-effective implementation procedures
Organic chemicals	Encouragement of VOC air emissions control	Scaling back of requirements for some heavily impacted segments
Lead in gasoline	Adoption of more stringent standard; earlier implementation	Banking and trading
Lead in drinking water	Adoption of a more stringent standard	Phasing in of monitoring and implementation; extended timing for lead pipe replacement
Sewage sludge		Scaling back of numeric criteria; reduction in number of pollutants regulated

* Taken from Morgenstern and Landy (1997).

In addition to the specific examples given in Table A.2, the USEPA (1987) highlights five areas where SEAs have influenced the development of regulations:

- guiding the regulation's development;
- adding new alternatives;
- eliminating alternatives that are not cost-effective;
- adjusting alternatives to account for differences between industries or industry segments; and
- supporting decisions.

The ability to draw such conclusions highlights the benefits of retrospective studies for the future development of SEA. The fact that different retrospective studies came to similar conclusions on the difficulties and advantages of SEAs provides an invaluable source for those conducting and using SEAs.

Cases in which SEAs did not influence decision-making

One reason the results of an SEA may not significantly influence a decision is that legislation requires action to be taken to protect health or the environment, regardless of the economic impacts. For example, although the US Clean Air Act amendments mandate the USEPA to assess the costs and benefits of regulation, they also mandate that a regulation must be implemented where there is scientific evidence that it would be beneficial to human health. As a result, the outputs of SEAs on regulations to improve air quality conducted by the USEPA may not influence the decision-making process. Box A.15 describes several instances where this situation has occurred.

Box A.15 Examples of SEA in the context of the US Clean Air Act

Coke emissions
The proposed regulation was aimed at reducing coke emissions released by production of steel by 90% by 1998. The economist employed to undertake the analysis used a computer model to generate probability distributions for cancer occurrence at coke plants. It was found that the occurrence of cancer would decrease, but that the health benefits would be small compared to the costs. The costs involved in avoiding cancer occurrences were expected to be between $10 million and 30 million per cancer case avoided. Although this is not a particularly cost-effective outcome, Congress had not given permission for the USEPA to base the final ruling on cost-benefit considerations, and so the analysis had little influence on the final outcome.

Nitrogen dioxide
Five regulatory options were considered as potential means of regulating emissions of nitrogen dioxide. The benefits were not monetised and were instead represented by the reduced emissions that would occur under different standards for nitrogen dioxide. Costs for the controls necessary to reduce emissions were calculated. The study concluded that there were no significant costs associated with introduction of the standard, and that no plant closings would occur as a result of the regulation. Although this conclusion supported the proposed regulation, it did not feature significantly as a part of the decision-making process.

Particulate matter
The USEPA used existing data to estimate the benefits of reducing concentrations of particulate matter in the atmosphere. Estimates were included for all categories of benefits where data were available, including human mortality and morbidity and reduced soiling and material damage in both the household and manufacturing sectors. Due to the large number of industries likely to be affected by regulation, the USEPA selected 16 where the impact was considered to be most significant for analysis. Of these 16 industries, ten were judged able to absorb the costs of implementation with no changes in product price or production levels, while the remainder were judged able to absorb the majority of the costs with minimal decrease in production costs. No recognised impact on small businesses or major change in industry structure was predicted. Again, although this conclusion supported the proposed regulation, it did not feature significantly in the decision-making process.

Source: USEPA (1987).

Another example of an SEA failing to influence regulations concerns food labelling. The SEA conclusion that small businesses should be exempt from food labelling requirements was, in effect, ignored by the decision-makers. This was because the relevant legislation was so specific about who was, and was not, eligible for exemption that the recommended action was not legally possible.

Similarly, banning of CFCs in aerosols can largely be attributed to public pressure rather than the effects of regulation. The situation was described by the US Food and Drug Administration (FDA) as "a simple case of negligible benefit measured against possible catastrophic risk." In this case, removal of CFCs was seen as essential and would have been undertaken regardless of the costs involved. This is despite the fact that the results of the USEPA analysis, in deciding whether and how to regulate CFCs, calculated the costs and benefits of national and international regulation. It concluded that a 50% reduction in CFC emissions would produce costs of $27 billion and benefits of $6.5 trillion.

Of course, the fact that an SEA did not influence a decision is not necessarily a criticism. It may simply be the case that the SEA found no significant differences between different options, or that the precautionary principle in decision-making outweighed the evidence of the SEA. Equally, information gathered systematically during SEAs can be helpful to decision-makers and others even where it does not directly influence a decision. Nevertheless, where SEAs regularly fail to influence decisions, questions may legitimately be raised concerning their scale and scope, and whether revised guidance is needed on how they should be commissioned and conducted.

A.5 Accuracy studies

Overview

Given the extent of potential sources of uncertainty, it would not be surprising to find examples where the benefits and costs predicted by an SEA were not realised in practice. The retrospective studies reviewed contained differing conclusions on the accuracy of SEAs in predicting the costs and benefits of regulatory changes. Examples of underestimates, overestimates and estimates that were broadly correct were found.

Morgenstern and Landy (1997) have identified three cases where there was sufficient information to judge the accuracy of *ex ante* estimates. For control of CFCs, although early analysis considerably overstated marginal control costs, estimates developed for the final RIA proved quite accurate and may even have underestimated the costs somewhat. For the phase-down of lead in gasoline, the decline in sales of leaded gasoline proceeded much more quickly than anticipated. Overall, the costs of the regulatory change were lower than predicted, based on the fact that refiners reduced their production of leaded gasoline so much more rapidly than expected. For reformulated gasoline, the USEPA's predicted cost differences were in line with those observed in the market.

MAFF (1996) found that, on average, actual costs of projects were 10% higher than had been estimated at the time of the latest appraisal (but 27% of schemes exceeded this 10% margin). The early appraisal stage was characterised by a tendency to underestimate the costs of projects; that is, there was a noticeable trend of increasing estimated costs as projects evolved.

A year later, MAFF (1997) found that the average cost variance (reflecting the difference between the cost at appraisal and the actual cost at scheme construction) was still calculated to be

22% over the cost at appraisal (at current prices, being much lower at 14% using constant prices via the retail price index), with the median variance at 6% over the cost at appraisal (or 1% using retail price index constant prices). One key weakness in many of the appraisals was a failure to consider maintenance and operating costs.

The response of industry to regulations

A particular source of inaccuracy in cost estimates arises from the difficulties that analysts have in predicting how industry will respond to a new regulation and thus the costs that it will face. This has led to significant errors in evaluating both costs and benefits. These problems arise from two main sources:

- lack of baseline information on industry structure or on the use of substances to be regulated; and
- the impacts of technological change.

An example of the first is given in Box A.16.

Box A.16 Lack of information on an industry for which regulations are proposed

When the UK introduced regulations to meet its obligations under the EU Directive on Packaging and Packaging Waste in 1997, it was estimated that around 9000 businesses would be required to take action under these regulations. The Compliance Cost Assessment for the regulations was based on that figure.

In 1998, the regulations were reviewed by the Advisory Committee on Packaging, which found that they would in fact cover some 19,000 businesses by the year 2000. The increase was thought to be partly due to changes in the structure of the economy and economic growth. It was also noted that figures were not certain because of the difficulty in predicting what type of industries use packaging. Although the costs per business were thought to be largely unchanged from the original assessment, the estimated total cost was increased to take account of the revised number of companies affected.

Source: DETR (1998).

Analysis of several case studies (Robinson, 1995) has shown that the ability of management to develop least-cost means of compliance tends to result in lower costs than originally anticipated. This is particularly the case where regulations allow flexibility in meeting requirements, for example through emissions trading (Hogue, 1999). When companies are faced with increasing compliance costs, there is a strong incentive for managers to try and reduce those costs while still complying with the regulation. An example is given in Box A.17.

In terms of the costs of meeting Montreal Protocol commitments to control ozone-depleting chemicals, a general finding is that the costs have been smaller than expected (UNEP, 1994; Cook, 1996; Hoerner, 1995). This trend has been attributed to some extent to unanticipated technical change, perhaps spurred on by market-based regulatory instruments. However, Hammitt (1997) finds that comparison of *ex ante* and *ex post* forecasts suggests "more tempered conclusions." Previous estimates by the USEPA are generally accurate, but may have underestimated aggregate marginal control costs.

Box A.17 Impacts of technological change

The UK Chemical Industries Association collected data on planned investment by the industry to meet environmental regulatory requirements from 1992 to 1996. It rapidly became clear, however, that predictions of investment needed to comply with new regulations were inaccurate. In 1992, actual spending on environmental investment was 10% of total investment. This figure was projected to rise to 24% by 1994. However, the actual proportion of investment allocated to environment in 1994 was only 12%.

One of the main reasons for the discrepancy was a move away from end-of-pipe technologies to building in compliance with regulatory requirements at the design stage. This made it difficult for companies to separate out the costs associated with environmental control. In the absence of incentives such as tax breaks for environmental investment, costs were allocated on an arbitrary basis. Because of these inaccuracies, the survey was discontinued.

Source: Chemical Industries Association (1997).

In contrast, the USEPA (1993) found that the total costs experienced by industry had been significantly underestimated in all six of the cases it examined. The main reason was that certain compliance strategies the SEAs had assumed would be adopted by companies were not followed in practice, and that only costs incremental to these strategies were estimated. An example of such a case is given in Box A.18.

Box A.18 Unexpected industry responses to water pollution controls

A retrospective study of an RIA concerning water pollution and the organic chemicals industry found that the USEPA had greatly overestimated the extent to which industry would achieve compliance by making in-process changes. Instead, the plants had complied by installing end-of-pipe treatment facilities. The reasoning behind this was that plant managers "did not want to tinker with an apparently delicate production process."

Source: Caulkins and Sessions (1997).

Another study assessing the economic consequences of amendments to the US Clean Air Act highlighted significant deviations in the estimated costs of reducing sulphur dioxide emissions to the air. At the time of implementation, it was estimated that the total costs of these emissions would be between $4 and 5 billion by 2010. A recalculation at the time of the amendments in 1990 estimated the total costs to be between $2 and 4.9 billion. Box A.19 sets out the reasons for these differences.

After publication of the Great Lakes Water Quality Regulation (in 1995), the USEPA was faced with challenges on the guidance and also a critique from industry of the benefit analysis (Castillo *et al.*, 1997). Many state environmental commissioners conducted their own analyses of compliance costs, concluding that the EPA's cost estimates were a little high but on the whole suitable.

Box A.19 Factors contributing to cost overestimates on the US Clean Air Act amendments

The costs to industry of compliance with the regulation were lower than anticipated because:

- The Act was based on tradeable allowances which authorised the emission of one tonne of sulphur dioxide. This allowance system facilitated competition across all emission routes, which in turn initiated the development of emission reduction technologies and measures independently of the regulation in attempts to remain competitive; and

- There was considerable flexibility in the timing of the emission reduction deadlines, which minimised disruption to industry and spread the costs of compliance over an extended time period.

Source: USEPA (1997).

A.6 Conclusions

There is little evidence from the retrospective studies as to whether the approach used for SEA influences the acceptability of the analysis results. However, there are common themes to the criticisms of SEAs raised in some of the studies. These focus on:

- incompleteness of data;
- failure to address uncertainty; and
- failure to consider a full range of options for action.

Although a number of organisations have developed technical guidance for the conduct of SEAs which address these matters, the studies appear to show that time and budgetary constraints do not always allow a full assessment to be undertaken. The legal context and other factors may also prevent the use of SEA results.

Often, however, it appears that the acceptability of an SEA will be most influenced by factors outside the SEA itself. For example, in analysing the lead in drinking water regulation published by the USEPA in 1991, Levin (1997) concludes that the SEA was only one factor in ensuring that the regulation was more stringent than the Office of Drinking Water had originally intended. The strictness of the regulation is attributed to five key factors (Levin, 1997):

- **quality and robustness of the analysis**. The scientific database on lead's health impact was extensive. The net benefits were substantial, even under very pessimistic assumptions. Eliminating any one benefit category, doubling costs or halving all benefit estimates still resulted in positive net benefits;

- **widespread USEPA support**. Given the EPA's previous experience with lead in gasoline in 1985, a number of senior managers were fully familiar with lead and had a commitment to reduce exposure;

- **analysis preceding decisions**. Unlike most RIAs, this analysis was completed before key decisions were made and before "bureaucratic momentum inhibited changes";

- **widespread public support**. Support remained strong for a stringent drinking water standard from both the public and environmental groups. External opposition was "relatively localised and light"; and

- **timing**. The analysis followed the highly regarded lead in gasoline study and the 1986 Amendments to the Safe Drinking Water Act, which highlighted lead as a concern. In addition a new director was appointed to the Office of Drinking Water, presenting a "window of opportunity".

In summary, retrospective studies suggest that:

- The failure to quantify the impacts of a decision explicitly can result in the inefficient use of resources. This has been highlighted in particular by consideration of the cost-effectiveness of health and safety legislation in the US, although it is more than likely that similar conclusions would be drawn for other countries where appraisals have failed to quantify such effects;

- There can be significant differences between *ex ante* estimates and actual *ex post* costs. Some examples indicate that estimates of costs to industry of regulations may be out by as much as 50%, owing to factors such as changes in technological development, overestimation of costs by industry, or individuals responding to new regulations in ways not predicted;

- Prediction, quantification and valuation of benefits can be even more problematic as in many cases the data required on dose-response functions, exposure rates and stock/population at risk required for quantification is unavailable. A second key issue in this regard is the failure of analysts to examine the level of uncertainty surrounding benefit estimates;

- Regardless of the detail and reliability of the SEA, decision-makers may still over-ride the conclusions of the analysis due to political and other constraints; and

- The failure to involve stakeholders from the beginning of an SEA can lead to significant problems later on in the decision-making process. However, there are also a number of issues surrounding such involvement (e.g. data collection and acceptability) which need to be considered within the overall SEA process adopted.

These findings are valuable in that they highlight not only the importance of particular activities within the SEA process, but also some of the "traps" analysts face when preparing and presenting the results of such analyses.

Despite the value of retrospective analyses, their more widespread use appears to be inhibited by budgetary constraints. During consultation, several government departments indicated their wish to undertake more work of this kind. The additional resource requirements of undertaking regular retrospective analyses was thought likely to create constraints on other areas of spending. Yet if conducting such studies does result in either reduced costs or improved benefits (or ideally both) for future risk management measures, then the cost of a retrospective study would be more than justified, particularly as many decisions concerning chemical risk management may involve significant socio-economic impacts.