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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.

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

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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

In January 1998, the OECD Advisory Group on Risk Management sponsored a Workshop on the Integration of Socio-Economic Analysis (SEA) in Chemical Risk Management. One of the recommendations made by Workshop participants concerned the development of a flexible framework for integrating socio-economic analysis in chemical risk management. This document was produced in response to that recommendation.

This is one of three documents produced (or being developed) by the OECD under its work on socio-economic analysis. *Guidance for Conducting Retrospective Studies on Socio-Economic Analysis* has already been published, and a technical guidance document on how to conduct an SEA is currently under development.

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TABLE OF CONTENTS

FIGURES, TABLES AND BOXES

FIGURES

TABLES

BOXES

LIST OF ACROYNOMS

ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
BCR	Benefit-Cost Ratio
CASPAR	Centre for the Analysis of Safety Policy and Attitudes to Risk
CBA	Cost-Benefit Analysis
CEA	Cost-Effectiveness Analysis
CCME	Canadian Council Ministers of the Environment
CEPA	Canadian Environment Protection Act
DETR	Department of the Environment, Transport and the Regions (UK)
DICE	Dynamic Integrated Climate Economy Model
DoH	Department of Health (UK)
DTI	Department of Trade and Industry (UK)
EA	Environment Agency (UK)
EC	European Commission
EFTEC	Economics for the Environment Consultancy
EPA	Environmental Protection Agency (US)
GE	General Equilibrium
HSE	Health and Safety Executive (UK)
I-O	Input-Output Model(s)
MCA	Multi-Criteria Analysis
MEE	Ministry of Environment and Energy (Canada)
MOPS	Multi-Objective Prioritisation System
NERA	National Economic Research Associates
NPV	Net Present Value(s)
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget (US)
PBDE	Polybrominated Diphenyl Ether
QALY	Quality Adjusted Life Year
RIA	Regulatory Impact Analysis
RPMS	Regulatory Process Management Standard
SAM	Social Accounting Matrix
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SMAA	Stochastic Multi-Attribute Acceptability Analysis
SMEs	Small and Medium-Sized Enterprises
SOP	Strategic Options Process
TB	Treasury Board (Canada)
TBT	Tributyltin
TSCA	Toxic Substances Control Act (US)
UNEP	United Nations Environment Programme
WCED	World Commission on Environment and Development
VOI	Value of Information

EXECUTIVE SUMMARY

Many countries have introduced requirements that new legislation and/or administrative regulations be subject to socio-economic analysis (SEA). This document presents an overview of the use of SEA in risk management decision making for chemicals. It is designed to assist decision makers who use SEA results to better understand how these results are obtained; to assist risk analysts and others to understand more about how the information they provide to the analysis is used; and to serve as a general reference for SEA practitioners and for stakeholders interested in (or involved in) SEA.

Socio-economic analysis can help determine whether the risk reduction measures under consideration are necessary or desirable. It addresses questions such as: How can the risks identified through risk assessment be reduced, and what will be the benefits? Who will be impacted by the measures being proposed? and What will be the costs of implementing various measures and how will the costs be distributed?

This document is based on experience already gained with socio-economic analysis in OECD countries. Although approaches to SEA vary among countries and among different regulatory agencies, 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.

A general explanation is given of the contribution SEA can make to chemical risk management. The activities that are part of each step in this process are described. Descriptions are also provided of analytical tools that may be used in SEA. How assessments of costs to industry, and of health and environmental effects, are carried out is examined in detail. SEA's role in chemical regulation is reviewed, along with other issues. Finally, a series of 'best practice' considerations are set out. These concern:

- use of substance-based versus impact-based approaches;
- risk estimation and characterisation;
- understanding chemicals' life cycles;
- identification of risk reduction options;
- identification of areas of impact;
- involvement of stakeholders;
- assessment of the implications of different measures;
- assessment of these measures' impacts;
- establishing standard assumptions;
- understanding equity and distributional impacts;
- establishing trade-offs;
- recommendations that could be made by the analyst;
- reporting procedures.

Chemical risk management - which is increasingly being carried out at the international level - can be a highly complex undertaking. Nevertheless, the procedures for assessing alternative risk management options need to be as open and accessible as possible to all relevant stakeholders. Socio-economic analysis can be a valuable mechanism for bringing about greater stakeholder involvement in the decision making process.

This 'framework' document was developed as part of OECD work on socio-economic analysis in the context of chemical risk management. A related technical guidance document (targeted especially to analysts) is in preparation. Another guidance document on the use of 'retrospective studies' of socio-economic analyses has recently been published.

GLOSSARY

Abatement cost function	The cost of abating a perceived problem, such as pollution or congestion, in the form of an equation/curve. Curves will tend to slope upwards at an increasing rate.
Appraisal	The process of defining objectives, examining options and weighing up the costs, benefits, risks and uncertainties before a decision is made.
Bequest value	The value placed by people on the continued existence of an asset for the benefit of future generations.
Catastrophic event	That which has a sudden, dramatic and widespread impact upon the environment.
Consumer surplus	The difference between the amount currently paid for a good or service and the maximum amount that an individual would be willing to pay.
Contingency	An allowance included in the estimated cost of a project to cover unforeseen circumstances.
Contingent valuation	The valuation of environmental change based on estimation of people's willingness to pay (or to accept compensation) for a specified effect, elicited via questionnaires and statistical techniques.
Cost-benefit analysis	A form of economic analysis in which costs and benefits are converted into money values for comparison over time.
Cost-effectiveness analysis	A form of economic analysis which compares the costs of alternative means of achieving pre-set goals, e.g. lives saved.
Cost of capital	The cost attributed to money raised for investment, expressed as an annual percentage rate.
Derogation	The exclusion or alternative treatment of those heavily impacted by a policy.
Discounting	The comparison of quantities which are distributed over time by converting them to a present value by applying a discount rate (set by Treasury in the UK).
Discount rate	The annual percentage rate at which the present value of a future pound, or other unit of account, is assumed to fall away through time.
Dose-response technique	Determines the economic value of changes in environmental quality by estimating the market value of the impact of those changes on the output of marketed resources (e.g. fisheries, timber, crop production).

Economic analysis	Aimed at evaluating all of the effects of a policy or project and valuing them in national resource terms. This takes place in a 'with' and 'without' framework.
Economic appraisal	An umbrella term which includes cost-benefit analysis and cost-effectiveness analysis. Should be contrasted with financial appraisal, which is restricted to cash flows.
Evaluation	The retrospective analysis of a project, programme or policy to assess how successful or otherwise it has been, and what lessons can be learned for the future.
Ex ante	Refers to predicted (or expected) values prior to, say, the introduction of a risk reduction measure.
Existence value	The value people place on the continued existence of an asset for the benefit of present generations.
Expected value	The sum of individual outcomes times their probability of occurrence.
Ex post	Refers to actual values as a result of, say, the introduction of a risk reduction measure.
Exposure	The means by which someone/something is exposed to a hazard.
Externalities	Goods which remain unpriced and thus are external to the market (i.e. 'free' goods such as those relating to the environment).
Financial analysis	The determination of the cash flow implications of a policy or project to the commissioning organisation, and of whether it is sustainable in that sufficient funds are generated to meet cash outflows.
General equilibrium	Type of analysis that looks at the economic system as a whole and observes all changes in prices and quantities simultaneously. Usually relies upon complex mathematical techniques.
Hazard	A situation or activity with the potential for harm.
Input-output model	Type of analysis that examines the inter-relationships between sectors of the economy. Usually represented as a series of linear production functions.
Intergenerational equity	One of the tenets of sustainable development, ensuring fair treatment between different generations.
Irreversible effects	The loss of an irreplaceable environmental feature (e.g. an ecosystem or species), and very long-term changes to the natural environment.
Least-cost alternative	The lowest alternative means of providing the same goods and services as the asset under consideration.

Market price approach	In a perfectly competitive market, the market price of a good provides an appropriate estimate of its economic value. In markets that are not perfectly competitive, economic value is calculated by the removal of subsidies or other price distortions.
Multi-criteria analysis	A decision aid which relies on scoring and weighting techniques to aid in problem evaluation.
Net present value	A term used to describe the difference between the present value of a stream of costs and a stream of benefits.
Non-use value	Values which are not related to direct or indirect use of the environment (consists of existence and bequest values).
One-off cost	A cost incurred once only throughout the analysis period. An example might be the replacement of capital equipment as a response to a risk reduction measure.
Opportunity cost	Value of a resource in its next best alternative use.
Option appraisal	A term used in some areas to describe any form of appraisal.
Option value	The value of the availability of the option of using an environmental or other asset (which is usually non-marketed) at some future date.
Peer review	Review of an appraisal by experts (in the public, private or academic sectors) to determine whether good practice has been followed, quantification is accurate, and so on.
Present value	The discounted value of a stream of future costs or benefits.
Real price	The nominal (i.e. cash) price deflated by a general price index or GDP deflator relative to a specified base year or base date.
Real terms	The value of expenditure at a specified general price level: that is, a cash price or expenditure divided by a general price index.
Residual value	The expected value of a capital asset at the end of the analysis or at some future date.
Resource costs	The cost of marketed goods or services (adjusted to economic prices) used as inputs to, or consumed as a consequence of, an action.
Revealed preference	Willingness to pay for something which is non-marketed, as revealed by other expenditure choices.
Risk	The likelihood of a specified (adverse) consequence.
Sensitivity analysis	The analysis of the effects on an appraisal of varying the projected values of the important variables.
Shadow price	An imputed value, where there is no market price, of a good, service or asset used in economic analysis (usually cost-benefit analysis).

Socio-economic impacts	Any impacts upon society/the economy as a result of a policy or project, such as price changes, welfare changes, employment, reduction in health impacts, and so on.
Stakeholder	Any interested party or party affected as a result of a policy or project.
Stated preference	The willingness to pay for something which is non-marketed, as derived from responses to questions about preference for various combinations of situations and/or controlled discussion groups.
Stocks and flows	Stocks are goods which will experience a one-off change in value. Flows occur annually and stem from the stock good (e.g. agricultural yields per year).
Switching point/value	The value of an uncertain cost or benefit at which the best way to proceed would switch, for example, from approving to not approving a project **or** from including or excluding some extra expenditure to preserve some environmental benefit.
Time preference rate	Preference for consumption (or other costs or benefits) sooner rather than later, expressed as an annual percentage rate.
Total economic value	The sum of use values (direct, indirect and option) plus non-use values (bequest and existence).
Uncertainty	Stems from a lack of information, scientific knowledge or ignorance and is characteristic of all predictive assessments.
Use value	The value of something which is non-marketed provided by people's actual use of it.
Welfare cost/benefit	Any effect on human well-being.

1. INTRODUCTION

1.1 Regulation of Chemical Risks

The widespread use of chemicals in the modern world has led to increasing concern over the potential effects of certain substances on both people and the environment. Although chemicals are ubiquitous in the natural world, there is no question that responsible chemical usage deserves attention. Well over 100,000 substances have been identified as having been in commerce throughout the world, although the number currently in commerce is much smaller. Roughly 2,600 chemicals are categorised within the European Union as 'high production volume' chemicals (over 1,000 tonnes produced per year), and between 15,000 and 20,000 are being produced in volumes between 10 and 1,000 tonnes per year. These chemicals include products which play an important role in agriculture, health care, home and personal care, manufacturing, education, recreation, and many other aspects of everyday life.

Data on volumes alone, however, are not adequate to determine whether a particular chemical poses a risk to human health or the environment. Such risks are context-specific and vary substantially, depending upon the substance of concern, its form, the nature of its use, and levels of exposure. For substances identified as potentially damaging, a range of regulatory controls exist at both national and international levels.

The approaches adopted in setting such controls vary across countries and regulatory agencies. In some countries, regulation is based on a precautionary stance, which requires that risks are minimised where the causes and mechanisms are unknown, or human health or the environment health is under threat. In the extreme, such an approach implies that many hazardous chemicals and activities are considered unacceptable because of the uncertain nature of associated risks. This type of approach to the management of chemical risks may neglect the benefits which the chemicals could confer on society. Less extreme interpretations of the precautionary principle stress the cost of taking precautionary measures, while others come closer to a 'safe minimum standards' approach.

Other approaches to risk reduction are technology-led: for example, where they are based on the concepts of making emissions 'as low as reasonably practicable' or the use of 'best available techniques not entailing excessive costs'. Both these concepts recognise, at least implicitly, that a balance should be struck between the costs involved in reducing risks and the benefits stemming from risk reductions. However, they provide no guidance on the level of environmental protection that is socially desirable, the level of risk to human health that is socially acceptable, or what constitutes excessive cost in terms of both public and private expenditure. Thus, risk versus benefit trade-offs are neither made explicit nor expressed in a way that allows direct comparison. As a result, decisions may be taken which imply widely varying valuations for the environment and for reductions in morbidity and mortality rates.

To address these concerns, many countries have adopted requirements that new legislation and/or administrative regulations be subject to socio-economic analysis (SEA) in order to help determine whether a proposed regulation is necessary or burdensome. In addition to requiring more rigorous analysis of costs and benefits, such initiatives call for better representation of, and consultation with, different stakeholders affected by the legislation. The OECD Council Recommendations on Improving the Quality of Government Regulation [Box 1(a)] reflect these requirements.

Box 1(a): OECD Council Recommendations on Improving the Quality of Government Regulation

In 1995, the OECD Council adopted a series of recommendations aimed at ensuring the quality and transparency of government regulations. These included a 'Reference Check-List for Regulatory Decision-Making' which set out the following criteria:

- Regulators should routinely estimate the total expected costs and benefits of each regulatory proposal and of feasible alternatives, and should make the estimates available in accessible format to administrative and political decision makers.

- Government should take a pragmatic and realistic approach to this issue. Qualitative assessments may be a useful beginning where analytical skills are low, where the cost of information collection is high, or where there is little consensus on how to value benefits.

- To the extent that distributive and equity values are affected by government intervention, regulators should make transparent the distribution of regulatory costs and benefits across social groups.

- Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses and trade unions, other interest groups, or other levels of government.

Source: OECD (1995a), as reported in OECD (1997)

1.2 Socio-Economic Analysis and Chemical Risk Management

Where there is concern over the risks posed by a particular use of a substance, a range of actions can be taken to reduce the risks. Such actions, ranging from banning a chemical through restricting its use to measures to control harmful effects, are not without costs. These may include increased production costs to industry and higher end product costs to consumers. If a chemical is banned, substitute chemicals may not be risk-free either, but may instead lead to a shift in the nature of the risk (e.g. from acute to chronic effects, or from human health effects to the effects on the environment - see, for example, Graham and Wiener, 1995). The implications of any specific risk reduction proposal therefore need to be made explicit. Because resources spent on reducing one risk cannot be spent on others, it is important that efforts are focused on managing the most significant ones.

In many cases, the risks posed by a chemical will be uncertain and decision makers may favour adopting a precautionary approach. There is no logical inconsistency, however, between favouring a precautionary approach to uncertain risks and, at the same time, adopting an approach that considers the benefits and cost-effectiveness of measures to reduce uncertain risks. Both approaches are incorporated in the use of 'value of information' techniques which examine the importance of uncertainty to the end selection of measures and the 'value' of reducing uncertainty. Such approaches are increasingly being recommended with regard to chemical risk reduction and in other environmental contexts. For example, they have been recommended for widespread use by the Presidential/Congressional Commission on Risk Assessment and Management under the US Clean Air Act.

In general, the aim should be to strike a balance between the costs involved in reducing risks, the known benefits of the chemical in the use(s) of concern, and the benefits stemming from risk reduction. Or, at the very least, it should be ensured that expenditure on risk reduction is cost-effective and that some minimum level of benefits is gained from a unit of expenditure across risk reduction policies.[1] In all cases, when faced with a decision concerning the control of a chemical, decision makers need to know if action is required or desirable, and if so, what the best course of action would be. This, in turn, requires answers to the following questions:

- What are the risks?
- How can the risks be reduced? Is regulation necessary, or can risk reduction be achieved through non-regulatory measures?
- Who will be impacted by reductions in risk?
- What are the costs of risk reduction and how will these be distributed across the chain of trade (or stakeholders) and over time?
- What are the benefits of reductions in risk?
- Is the risk reduction justifiable? and
- What is the best risk reduction strategy?

The first of these is answered through risk assessment. The remaining questions can be addressed through SEA, which should provide a rational basis for weighing the advantages and disadvantages of choices. Studies undertaken in the US highlight just how valuable such analyses can be in improving regulatory decision making. For example, Morgenstern (1997) describes a study of the use of SEA in relation to 12 proposed regulatory changes to protect human health or the environment. The study concluded that 'In all cases examined, the economic analyses did, in fact, contribute to improving the rules: the value of such improvements likely dwarfs the one-time cost of conducting the analysis.'

The most commonly used forms of SEA are cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA), with some forms of multi-criteria analysis (MCA) also used in some OECD countries. The key differences between these approaches are as follows:

- CBA provides a framework for comparing both the costs and benefits of a proposal as they would be measured in economic resource or opportunity cost terms. The nature of the analysis may range from one which is mainly qualitative to one which is fully quantitative, with the aim being to determine if a proposal is worthwhile from a social perspective. That is, are the benefits to society as a whole greater than the costs?

- CEA is widely used in assessing proposed environmental measures. In some cases, it is used to determine the most cost-effective means of achieving pre-set targets or goals, which are often defined by governmental guidelines or legislation. CEA is also used to provide evidence concerning the cost-effectiveness of a given measure (without the use of any pre-set goals). This allows the regulator to make a judgement on the reasonableness of a measure, as compared to alternative measures, with respect to the level of benefits achievable at a given level of cost.

- MCA provides the basis for a semi-quantitative or qualitative analysis. It uses techniques ranging in sophistication from checklists to trend analysis to intricate mathematical

1 A range of different decision rules could be adopted, which would lead to different interpretations of what constitutes an appropriate balance and hence the desired approach to standard setting. See, for example, Graham *et al.*, 1988, which examines different approaches to standard setting with regard to cancer risks.

procedures. Like CBA, MCA can convert the potential impacts of a proposed measure into a common unit of measurement to allow direct comparison of the measure's critical elements.

1.3 Aims of this Document

This document has been prepared in response to a request from the OECD Workshop on SEA[2] (later endorsed by the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology) to highlight ways in which SEA can improve chemical risk management in general. It provides a general discussion of the key elements of socio-economic analysis, drawing on guidelines already existing in OECD countries and the experience that has been gained through applying them. The document focuses on tools for reducing public health and environmental risks to society as a whole (and to particular at risk groups within society), rather than on financial risks to business or individual organisations.

The document is designed to:

- assist decision makers who use the results of SEA to understand the processes underlying the results;
- help providers of the information used in SEA, including risk analysts, to understand the context in which their information is used; and
- act as a general reference source for practitioners of SEA and stakeholders interested in the SEA process.

More detailed guidance on SEA methodologies and techniques is given in a range of existing publications from the OECD and Member countries. Reference to these sources (listed in Section 9.1) is made throughout the text, with other useful sources listed in the Bibliography (Section 9.2). A forthcoming publication will provide further technical guidance on the application of the tools discussed here. This publication will be targeted at those analysts tasked with preparing SEAs.

This document begins by summarising current SEA practices in OECD countries. A framework is set out, describing how SEA fits into the overall process of chemical risk management. The activities involved in each step of this process are briefly discussed. Descriptions are then provided of the different analytical tools which can be used in SEA, including economic appraisal methods and multi-criteria analysis. This is followed by more detailed examination of the estimation of costs to industry, the assessment of health and environmental effects, and some of the key issues involved in preparing SEAs. The document ends with a review of the role of SEA in chemical regulation. A series of 'best practice' considerations are presented.

2 OECD Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management, 7-9 January 1998, London.

2. REGULATORY AND POLICY FRAMEWORK

2.1 Introduction

Risk assessment, SEA and risk management activities are undertaken at a range of different levels. Industry has adopted the use of such tools internally to ensure good environmental management and worker and product safety. International agreements and conventions, and national legislation, provide the regulatory imperative underlying their use in specific contexts.

This section presents a general overview of the degree to which the various methodologies falling under the general heading of SEA are already used in individual OECD countries. Brief summaries are also given of some key initiatives at the international level, specifically those of the OECD and European Commission.

2.2 OECD Initiatives on the Use of SEA

The OECD first established its programme of work on chemical safety in 1971. In 1990, the OECD Council Act on Co-Operative Investigation and Risk Reduction formally established the risk reduction programme, which lays out the guiding principles for all such actions. In particular, in that Act the Council:

- decided that Member countries shall establish or strengthen national programmes aimed at the reduction of risks from existing chemicals to the environment and/or health of the general public or workers;

- recommended that Member countries collaborate to develop common criteria to determine those chemicals suitable for concerted risk reduction activities; and

- recommended that, where appropriate, Member countries undertake activities to reduce the risks of selected chemicals, taking into account their life cycle. These activities would include promotion of cleaner products and technologies, emission inventories, product labelling, limitations on use, economic incentives, and the phase-out of certain chemicals.

In 1996, the OECD Risk Reduction Programme became the OECD Risk Management Programme. One of the outcomes of this change is that the programme now gives priority to issues associated with problematic uses of a chemical, rather than to the chemical in all its applications. Work therefore focuses on exposures to particular chemicals in particular applications (referred to as ‘priority chemical exposures of concern’). It also focuses on areas where particular chemical uses would benefit from (regulatory or voluntary) risk reduction actions that could be implemented at the national or international levels.

At the same time, an Advisory Group on Risk Management was established to further develop and oversee implementation of a programme of work concerning the development of appropriate risk management strategies. This Group was tasked with:

- developing criteria for, and identifying and selecting, priority chemical exposures of concern;

- developing effective risk reduction actions (regulatory and non-regulatory, at the appropriate level) based on proper risk assessment;

- considering new approaches to problem identification, priority setting, and evaluation of the effects of risk reduction measures; and

- developing methodologies for risk communication and socio-economic analysis of risk reduction options.

2.3 SEA Requirements in OECD Member Countries

2.3.1 Overview

The use of SEA is a well established part of regulatory decision making in many OECD countries, as indicated in Table 2.1. This table presents data collected as part of a study for the OECD (OECD, 1997). A study was also undertaken for the European Commission (RPA, 1998) involving a survey of 19 countries (the 15 EU Member States, Australia, Canada, Japan and the United States). This study found that regulatory appraisal practices, in general, vary considerably over the different countries. For example:

- countries make use of a wide range of appraisal approaches, including compliance cost assessments, CBA, CEA, checklists, simple scoring and weighting techniques, multi-criteria analysis, and other qualitative/semi-quantitative approaches;

- some countries have strict requirements for the use of economic appraisal across policy areas, resulting in highly developed systems for co-ordinating appraisal activities; while

- in other countries, appraisals are carried out on a more ad-hoc basis, with little formal intra- and/or interdepartmental co-ordination.

A number of countries indicated that they currently rely on some form of quantitative impact analysis (e.g. estimation of compliance costs), with several also indicating that they are considering the adoption of, or have already turned to, the use of the more sophisticated economic appraisal techniques such as CEA and CBA. As Table 2.1 indicates CEA and CBA are already used in a number of countries. In practice, the use of full quantification within CBA is considered to be most advanced in Australia, Canada, the UK and the US. These countries more readily rely on quantification and, where possible, apply economic valuation techniques in order to place monetary estimates on changes in risk to the environment and human health.

Table 2.1: Type of Appraisal Applied to Environmental Regulations by Selected OECD Countries and the European Union	
Country	**Methods**
Australia	Benefit-cost analysis applied at the Commonwealth level and by certain States to bills and lower-level rules where costs to business may be high.
Austria	Fiscal analysis recommended for bills. CBA may be used for long-term planning issues.
Belgium	Analysis of draft legislation may include a cost analysis and, in some cases, use of CBA/CEA.
Canada	Regulatory Impact Statements accompany draft and final regulations summarising any analysis prepared, which may be in the form of a Business Impact Test, Regulatory Cost Accounting Protocol or other equivalent analysis. CBA/CEA is used for standard setting and hazardous chemicals regulation.
Denmark	General impact analysis required for new legal proposals which, inter alia, may require both an economic study and an environmental impact assessment.
European Union	Treaty on European Union (article 130 r.3) requires that the costs and benefits of each proposed regulatory action be assessed. Assessment of advantages and drawbacks is required where marketing and use restrictions are proposed for existing substances under EEC 793/93.
Finland	Economic and environmental assessment of all public decisions, including bills and lower level rules.
Hungary	Economic evaluations of proposed environmental regulations required under the Act on Environment.
Ireland	Environmental impact assessments required.
Italy	Cost-output analysis used, with emphasis placed on fiscal costs.
Japan	General impact analysis used as necessary to develop rules and social regulations.
Korea	No formal approaches to SEA currently exist, although use of different methods is under examination.
Mexico	CBA and CEA applied to 'business-related' procedures and requirements.
Nether-lands	General impact analysis for bills and lower level rules. Regulatory impact analyses of likely financial effects of new regulations on industry and trade. Such analyses may also cover environmental impact assessments of proposed regulatory changes originating from non-environment Ministries.
New Zealand	Fiscal analysis and compliance cost assessment applied to draft laws originating from Cabinet.
Norway	Economic impact assessments undertaken of proposed regulations, which may take the form of cost-benefit analysis. Environmental policy instruments also reviewed in relation to goal achievement, cost-effectiveness, distributional effects, and effects on technological development.
Portugal	Fiscal analysis of bills and lower-level rules; also environmental impact assessments of certain bills.
Spain	Financial analysis of effect of regulatory proposals on public budget.
Turkey	General impact analysis for bills and lower level regulations.
United Kingdom	Compliance cost assessment and fuller regulatory appraisal of new and amended regulation. Economic appraisal required of new legislation, generally using CBA, but may also take the form of a CEA or include use of multi-criteria techniques.
United States	Regulatory analyses and CBAs required for actions subject to Executive Order 12866 when not specifically prohibited by the enabling statute. In other contexts, EPA carries out more specific cost and cost-benefit analyses in accordance with relevant Acts.
Sources: Based on data presented in OECD (1997) and supplemented by additional data provided by Member Countries	

Although the table lists approaches to environmental regulatory appraisal in general, the European Commission study (RPA, 1998) suggests that similar conclusions can be drawn with regard to chemical risk management. Indeed, if anything, there appears to be a greater tendency to use SEA in this field. This stems in part from the legislative and policy requirements existing in some OECD countries (e.g. Canada, the UK and the US). It is also a result of international requirements, such as those within the EU concerning regulation of dangerous substances and the need to assess the 'advantages and drawbacks' of restrictions on the marketing and use of such substances. Further details of some country-specific requirements and of the EU requirements are given below.

2.3.2 SEA Requirements in Canada

In Canada, SEA is integrated into the development of legislation to a significant degree. Since 1977, Canada's Treasury Board (TB), which has oversight responsibilities over other government ministries, has required that all major new health, safety and related regulations are subject to SEA.

The TB's Regulatory Policy requires that 'the benefits [of a proposed regulation] outweigh the costs to Canadians, their governments and businesses.' To ensure that SEA, and other requirements of the Regulatory Policy, are carried out, the TB has developed guidance for regulatory authorities to follow known as the Regulatory Process Management Standards (RPMS). In the first instance, RPMS requires consideration of whether intervention is required at all. Where intervention can be justified, it is strongly advised that the benefits of proposed actions are assessed against any costs, and that 'regulatory effort is being extended where it will do the most good.' Where assessment shows that the benefits of an action do not exceed the costs, supplementary justification of why a particular action has been chosen is required.

The TB produces a range of documents to assist federal departments in meeting the Regulatory Policy (Government of Canada, 1995). One of these is the *Benefit-Cost Analysis Guide for Regulatory Programmes* (Consulting and Audit Canada, 1995), which provides guidance on the extent to which costs and benefits must be assessed in accordance with the expected level of impacts associated with a proposal. Such analyses include a Business Impact Test to assess the effects that major regulatory proposals would have on the business community. The Guide is not prescriptive; both qualitative and quantitative analyses can be undertaken. The objective of SEA is defined as the presentation of all relevant information, both quantitative and qualitative, to ministers and the public. A summary of the SEA is provided for consideration by Ministers, prior to regulatory approval. The Regulatory Policy applies to all federal departments.

In addition to these general requirements, Environment Canada and Health Canada have developed a process to meet their joint requirements, under the Canadian Environmental Protection Act (CEPA), to 'establish environmental objectives and identify the most cost effective and efficient options for achieving those objectives for managing CEPA toxic substances' (Sustainable Futures, 1998).

The Strategic Options Process (SOP) integrates the use of economic analysis and multi-stakeholder involvement into the development of risk reduction measures for substances defined as toxic by the CEPA. Using SOP, risk management strategies have been developed for over 20 toxic substances, although not all have yet been implemented.

As there is no explicit requirement for a particular methodology to be applied, a range of qualitative and quantitative techniques are used. The process does, however, acknowledge the need for gathering (and, where necessary, developing) good quality data for evaluating costs and

benefits. Through extensive stakeholder involvement, the process has also resulted in a better understanding and acceptance of the various techniques, in particular economic appraisal methodologies, within the regulated community. In addition, Health Canada's Bureau of Chemical Hazards uses SEA routinely when risk management options are being evaluated.

Canada's provinces, which maintain significant responsibility for environmental and other policies, also carry out SEA, although there is considerable variation in the tools used. The Ontario Ministry of Environment and Energy (MEE), for example, is using SEA to assist in the development of about 35 new or revised air quality standards and has used it in the past to develop effluent limits for industrial plants.

The Canadian Council of Ministers of the Environment (CCME), which brings together federal and provincial ministers, provides a forum for co-ordination between the provinces. The CCME, which has focused in recent years on the management of toxic substances, has proposed guidelines for SEA use in:

- prioritisation of emissions reduction opportunities;
- selection and design of policy instruments;
- interim and final targets and standards; and
- time schedules for implementing policy instruments.

2.3.3 SEA Requirements in the United States

US Executive Order 12866, supported by a working paper released in 1996 by the Office of Management and Budget (OMB) titled *Economic Analysis of Federal Regulations Under Executive Order 12866* (Bureau of National Affairs, 1996), establishes a regulatory philosophy for risk management which is spelled out in its Principles of Regulation. These are outlined in Box 2(a). The aim is to provide the basis for an improved regulatory plan that 'protects and improves [the American people's] health, safety, environment, and well being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society' (White House, 1996).

Since the early 1980s, economic assessment has played a role in decision making concerning control of toxic substances in the US, with regard to regulations under both the Consumer Product Safety Act and the Toxic Substances Control Act (TSCA). Under Section 6 of TSCA, the Environmental Protection Agency is required to balance the risks and benefits of the use of a substance with the costs of regulatory control. The risk management framework followed for managing the risks of existing chemicals has included the following steps (Axelrad, 1993), although it is not a formal process:

i) identification of chemicals for regulatory control;
ii) 'use and substitutes' analysis;
iii) risk assessment;
iv) economic assessment;
v) risk of substitutes analysis; and
vi) regulatory impact analysis.

Box 2(a): US Office of Management and Budget Principles of Regulation

The Principles of Regulation can be summarised as follows (Barnard, 1996):

- In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of risks posed by the various substances or activities within its jurisdiction.

- When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective.

- Each agency shall assess both the costs and benefits of the intended regulation and, recognising that some of these are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

- Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities, consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

Source: Barnard (1996)

Where a need for regulatory control is identified, *use and substitutes information* is developed. This consists of information on the chemical of concern in terms of production, imports, exports, and the nature and extent of use. In addition, possible substitutes are identified and their advantages and disadvantages assessed. The use and substitutes information is a major input to the economic assessment.

The *risk assessment* summarises risks to human health and the environment associated with the chemical and highlights any related uncertainties. With respect to human health, risks are described in terms of either population risk (an aggregate measure of the projected frequency of effects among all those exposed) or individual risk (the probability of an exposed individual experiencing the adverse effect). This information is another important input to the economic assessment, and it provides a basis for the assessment of benefits.

The aim of the *economic assessment* is to identify different regulatory options and develop estimates of their costs and benefits. The analysis should include:

- a profile of the chemical in terms of production, uses, substitutes and existing controls;
- a summary of the risks and possible regulatory options;
- the costs and benefits of these options;
- sensitivity analysis; and
- a summary of impacts on trade, small entities, innovation and equity.

One of the key requirements of the analysis is that it is transparent, providing a thorough explanation of the methodology and key assumptions, as well as clearly presenting the data used and calculations involved in deriving the costs and benefits.

The *risk of substitutes* analysis sets out the risks associated with potential substitutes, the aim being to ensure that their use results in reductions in risk. This analysis can use information from the economic assessment to identify the type and magnitude of chemical substitution. The nature of the decision making process is iterative, so this risk information is also an important input to the assessment of benefits of possible regulatory options. As such, this forms a key input to the decision making process.

An Economic Analysis, previously referred to as a Regulatory Impact Analysis (RIA), is only required for 'major' regulations. These are defined by Executive Order 12866 (replacing Executive Order 12291) as those which are likely to result in:

- an adverse (cost) impact on the economy of $100 million or more;
- a major increase in cost or prices to consumers, individual industries, federal, state or local government, or a geographic region; or
- significant adverse effects on competition, employment, investment, productivity, innovation, or the performance of US-based enterprises in domestic or export markets.

While the economic assessment provides detailed evidence for the regulatory decision, the Economic Analysis provides an overview of the decision making process and summarises the key issues taken into account. However, the Economic Analysis extends the economic assessment by providing a more detailed and quantitative assessment of the impacts of the proposed measures.

2.3.4 SEA and Chemical Risk Management in the EU

EU legislation requires that the risks associated with chemicals and other dangerous products that are marketed be assessed and, where appropriate, reduced. The legislative framework is provided by the Directive on dangerous substances and preparations (67/548/EEC) and associated implementing Directives and Regulations (the key ones being Directive 93/67/EEC, Regulation (EEC) No. 793/93 and Regulation (EC) No. 1488/94[3]). The dangerous substances Directive was originally conceived as a means of harmonising specifications which could otherwise create obstacles to free movement of goods. However, subsequent amendments have been aimed at ensuring chemical safety and environmental protection. The other Directive of direct relevance to risk management is 76/769/EEC on the marketing and use of dangerous substances and preparations. Under this Directive, bans and other controls can be placed on dangerous substances. Few Member States have legislation in place at the national level to regulate chemical substances.

In a Working Paper on Risk Management (European Commission, 1997), Directorate General III of the European Commission defined risk management within the framework of Directive 76/769/EEC as 'the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of the risk assessment with additional data on social, economic and political concerns to reach a decision.' This implies the following approach to risk management:

- identification of chemicals for consideration;
- risk assessment;
- risk evaluation; and

3 The requirements of Directives 67/548/EEC and 76/769/EEC apply to all dangerous substances and preparations except those covered by product-specific directives incorporating the necessary requirements, such as pesticides.

- risk mitigation or reduction.

Under Article 10 of Council Regulation (EEC) No. 793/93, where marketing and use restrictions are recommended, 'an analysis of the advantages and drawbacks of the substance and of the availability of replacement substances' is required. More generally, the Commission has 'engaged itself to carry out a comprehensive risk assessment and an adequate analysis of the costs and benefits prior to adoption or proposal of measures affecting the chemical industry.' The form of such analyses is left open, as is the detail regarding what should be considered.

The document *Technical Guidance on Development of Risk Reduction Strategies* under EEC 793/93 (EC, 1998) provides general guidance as to what should be considered in such assessments. It puts forward a five-step approach to risk management which includes the consideration of socio-economic issues as summarised in Box 2(b).

The document also highlights the differences in attitude which exist across the various Member States concerning the use of socio-economic analysis. For example, some favour a precautionary approach and call for action, including when evidence for the existence of risks is highly disputed, while others place more stress on adopting an approach which insists that actions which could entail large costs should not be taken without a clear benefit (EC, 1998). As a result, there are differing views within the EU on the level of assessment which should be undertaken as part of the risk management process and the assessment of 'advantages and drawbacks', and the treatment of uncertainty within such assessments. For example, some Member States prefer a simple 'check box' technique, while others prefer as fully quantitative SEA as possible.

Box 2(b): Developing a Risk Reduction Strategy under EEC 793/93

Step 1: Identify the specific stages in the manufacture, storage, distribution, use or disposal of the substance which have been highlighted by the risk assessment as giving rise to risks that need to be limited.

Step 2: Take account of any existing risk reduction measures, and identify the options available for effectively reducing the risks which need to be limited.

Step 3: Identify the administrative, legal and/or other tools with which any recommended action can be taken.

Step 4: Select the most appropriate risk reduction strategy by evaluating the list of potential effective measures and implementation methods against the following criteria: effectiveness, practicality, economic impact, and monitorability.

Step 5: If marketing and use restrictions are recommended, prepare an analysis of advantages and drawbacks and of the availability of alternatives.

Source: European Commission (1998)

The Working Paper on Risk Management (1997) attempts to overcome these differences by setting out the views of Directorate General III on the assessment of advantages and disadvantages. Key points are (EC, 1997):

- the advantages of a proposed restriction can be understood as the extent to which the risks will be limited, allowing for any increase in risk to human health and the environment

arising from increasing use of replacement substances;

- additionally, avoidance of future costs of environmental remediation and health care presently incurred in dealing with the existing risks, as well as advantages from the development of alternative technologies, have to be taken into account;

- drawbacks of the restriction would be any reduction in the benefits provided by the substance as it is currently used, and additional costs to industry, consumers, the regulator and society, allowing for benefits from an increasing use of replacement substances; and

- when the data used in the risk assessment are very limited, and/or the risks are obviously high and unacceptable, a qualitative analysis is sufficient, with further quantification neither possible nor necessary. However, when marketing and use restrictions are under discussion, the analysis should be quantified as completely as possible in monetary terms with the use of cost-effectiveness analysis or CBA, as appropriate.

3. A FRAMEWORK FOR CHEMICAL RISK MANAGEMENT

3.1 The Decision Context

3.1.1 The Role of 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. Such a systematic approach enables decision makers to determine the adequacy of the information available and to identify any important gaps.

In the context of chemical risk management, one aim of SEA is to assist in balancing the costs and benefits of potential risk management measures. In achieving such a balance, a number of factors need to be considered, including:

- the nature of the risk – this includes whether the risks are short- or long-term in nature, reversible or irreversible, voluntary or involuntary, cancer-causing, well known and understood, more or less predictable,[4] etc.;

- the costs of risk reduction - the adoption of a risk reduction measure is likely to impose costs on one or more sectors, and may vary in magnitude and significance for different measures;

- the nature of benefits - benefits will stem from the reductions in risk and may include reduced adverse health effects, reduced environmental impacts and, in some cases, longer-term benefits to industry from technological change;

- the risks posed by substitutes - a risk management measure which results in switching to

4 Although all risks are inherently uncertain, the level of confidence with which particular outcomes are predicted varies enormously. For example, the numbers of fatalities/injuries associated with road traffic incidents can be reasonably well predicted, while those associated with long-term exposure to certain chemicals cannot.

substitutes could generate additional risks, or simply shift risks from one receptor group to another; and

- the risk/benefit distribution - those who gain from risk reduction are not likely to be the same as those who lose, making consideration of the distribution of risks, costs and benefits important.

3.1.2 Where Can SEA Be Applied?

The US EPA has indicated a number of specific areas where SEA can influence the development of risk management measures. With regard to a specific regulatory proposal, these are (Morgenstern, 1997):

- guiding the development of a regulation from first proposal stage, including identification of new, alternative measures for risk management;
- eliminating measures which would not be cost-effective or feasible/acceptable for other reasons;
- adjusting proposed measures to account for differences between industries or industry segments; and
- supporting the end decisions.

At a higher level, SEA can be used to examine and compare the effectiveness of regulatory programmes. Box 3(a) describes the ways SEA is used by the Ontario Ministry of Environment and Energy in this manner.

Box 3(a): Use of SEA in Air Pollution Regulation in Canada

The Ontario Ministry of Environment and Energy (MEE) uses SEA, particularly cost-benefit analysis, to assist in the following activities:

- identifying (and avoiding) policies and programme designs whose benefits clearly are not commensurate with costs;
- determining how much money and effort should be directed at a particular programme or policy;
- determining whether changes in regulatory requirements are economically justified;
- ranking different programmes and projects that have similar goals and objectives; and
- comparing the quantitative estimates of the benefits of a particular environmental programme or policy option with similar estimates developed for different types of government activities and programmes, to determine regulations' cost-effectiveness.

Source: Donnan (1996)

3.2 Risk, Sustainability and Other Decision Criteria

3.2.1 Introduction

Risk criteria are often used to support decisions concerning whether the baseline risks associated with a particular chemical may require some form of risk management. In other words, they help characterise levels of risk in terms of their potential acceptability or unacceptability. Such criteria may relate to risks either to human health or to the environment. However, where a risk is identified as potentially unacceptable, this should not act as the sole driver to decision making; other information is required for deciding how that risk should be managed.

Similarly, other decision criteria may act as a backdrop to decision making and influence the type of measure adopted for mitigating risks. These include criteria related to sustainability and sustainable use of chemicals, economic growth and acceptability, equity and fairness, regulatory implications and political acceptability.

3.2.2 Human Health Risk Criteria

In general, the consensus is that there are three levels of risk:

- a level of risk which is so high as to demand immediate action, often referred to as an 'unacceptable', 'intolerable' or '*de manifestis*' risk;

- a level of risk which is so low as to be regarded as trivial, referred to as an 'acceptable', 'negligible' or '*de minimis*' risk; and

- a level of risk between these extremes, where consideration should be given to the costs and benefits of risk reduction measures.

With regard to protection of human health, although risk criteria are used in several countries to determine whether or not a risk is 'unacceptable', comparing one set of criteria with another is often a complex task. In the discussion that follows, a distinction is made between risks to an individual and to society as a whole. Concerning risks to an individual, we may define individual risk as *the frequency (probability) at which an individual may be expected to sustain a given level of harm from the realisation of specified hazards.* By way of example, the risk of an individual being killed by lightning in the UK is one chance in 10 million per year.

Concerning risks to society as a whole, the situation can become very complex. One attempt to categorise the risks of interest is provided by Ball and Floyd (1998), as shown in Table 3.1.

As can be seen from the table, the concept of societal risk is particularly important when considering the potential of incidents associated with hazardous activities that result in large numbers of fatalities. Examples of such activities include the operation of chemical and nuclear plants, transport of hazardous materials, operation of passenger aircraft, etc. In Europe, it is possible that the concept of societal risk might be extended to account for environmental damage resulting from major accidents in response to recent legislation.[5]

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5 Specifically, EC Directive 96/82/EC on the Control of Major Accident Hazards Involving Dangerous Substances, dated 9 December 1996, also known as the COMAH or Seveso-II Directive. It is worth noting that in a recent review of societal risk criteria (Ball and Floyd, 1998)

Table 3.1: Risks to Society - A Possible Typology				
Term	**Nature of risk**	**Risks associated with**		**Possible basis for criteria**
		'Normal' activities?	**Accidents?**	
Collective risks	'Diffuse' risks associated with exposure to hazardous materials	Yes	No	Individual risk – possibly aided by CBA, CEA or MCA
Societal risks	'Simple' risks associated with hazardous installations/activities	No	Yes	Numerical criteria based on fatalities
Societal risks	'Diverse' risks associated with hazardous installations/activities	No	Yes	Numerical criteria based on 'harm'
Societal concerns	Overall impacts/risks of technologies/strategies	Yes	Yes	Political judgement – possibly aided by MCA
Source: Ball and Floyd (1998)				

Concerning the use of chemicals and substances in 'everyday life', attention is usually focused on the level of individual risk, although risk assessment results can also be presented in the form of 'collective risks' by simply considering the level of individual risk and the size of the population at risk. For example, if the individual risk of developing a fatal cancer was one chance in 100 million per year and the population at risk was 100 million, the collective risk would be one cancer per year.

Estimated risk values are usually expressed as either chances per year or chances per lifetime. The latter particularly applies to the expression of cancer risks, in which the concern is often related to exposure and effects over a lifetime. Given a life expectancy of, say, 80 years, it can be seen that conversion from an annual to a lifetime risk can be achieved by dividing by 80, as shown in Table 3.2. For workplace risks, assuming a 45-year working life, the conversion requires division by 45.

A summary of some current individual risk criteria is presented in Table 3.3. It is important to stress that these criteria are, in effect, actual or implied government guidelines which are applied with varying degrees of rigour. Furthermore, the criteria are applied to 'members of the public' rather than to 'workers'. This distinction is sometimes made with reference to 'involuntary' and 'voluntary' risks. Broadly speaking, the limits for workers (who 'voluntarily' expose themselves to risks) are a factor of ten (or more) higher.

From Table 3.3, it can be seen that the criteria levels of acceptable/unacceptable risk vary by type of risk and by country. There is broad agreement that risks above 1 chance in 100,000 per year (1 in 10,000 for workers) are 'unacceptable'. Risk levels of less than 1 chance in 100 million per year are 'acceptable', although a risk of 1 chance in 1 million per year is 'acceptable' in many places.

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only one country, Switzerland, was identified as having developed societal risk criteria which incorporated environmental damage.

Generally, the level of 'unacceptable' risk corresponds to about 10% of the risk level associated with normal 'voluntary' risks (driving, working, etc.) and is similar to the higher 'involuntary' risks (being murdered, hit by a car, etc.), as shown in Table 3.4. These figures represent the 'average', and clearly there will be significant lifestyle variations.

In the US, the situation is somewhat different in two respects. Firstly, although the regulatory bodies do not use explicit risk criteria, estimated risk levels are often used to help justify specific regulatory actions in relation to chemical risk management. Secondly, the focus in the US is very much on 'excess lifetime cancer risks'. However, in many past US regulatory decisions, limits of acceptability are in line with those presented in Table 3.3 (see, for example, Travis, *et al.*, 1987).

Table 3.2: Individual Risk Conversion

Lifetime risk	**Equivalent individual annual risk (per year over 80 years)**	**Equivalent individual workplace risk (per year over 45 years)**
1 in 1,000	1 in 80,000	1 in 45,000
1 in 10,000	1 in 800,000	1 in 450,000
1 in 100,000	1 in 8 million	1 in 4.5 million
1 in a million	1 in 80 million	1 in 45 million

In summary, for existing technologies and 'known' risks, it is usually the case that legislation or current best practice (as prescribed in authoritative Codes of Practice) ensure that measures are considered for mitigating those risks that are likely to be regarded as 'unacceptable'. Similarly, the presence of trivial risks is accepted as a matter of course. The concern is therefore over what approaches are to be used in mitigating the non-trivial risks, which fall into the 'grey' area where a balance needs to be reached between risks, costs and benefits, and other wider decision criteria.

Table 3.3: Examples of Actual and Implied Individual Risk Criteria (per year of becoming a fatality or contracting a fatal cancer)

	Nature of risk	Limit of unacceptability	Limit of acceptability	Criteria applied in between	Ref:
Hong Kong	Residents close to hazardous facilities	1 in 100,000		n/a	1
Netherlands	Residents close to hazardous facilities	1 in 1 million	None, but until recently: 1 in 100 million	ALARA*	2, 5
Netherlands	Cancer risks	not given	1 in 100 million	n/a	2, 3
UK	Residents close to hazardous facilities	1 in 100,000	0.3 in a million	ALARP**	4
UK	Radiological risks	1 in 100,000	1 in 1 million	ALARA(?)	5
Australia (some States)	Residents close to hazardous facilities	not given	1 in 1 million	n/a	6

* As low as reasonably achievable
** As low as reasonably practicable
Sources:
1. Hong Kong Planning Department (1993)
2. Ale B (1992)
3. Personal communication (1997)
4. Health and Safety Executive (1989)
5. Cooper JR et al. (1996)
6. New South Wales (1992)

Table 3.4: 'Everyday' Risks in the UK

Level of individual risk	'Voluntary' activities	'Involuntary' activities
1 in 10,000 per year	Driving, working in non-office environment, being at home	
1 in 100,000 per year		Being murdered, being run over
1 in 10 million per year		Being struck by lightning

3.2.3 Environmental Risk Criteria

Human health concerns, rather than environmental concerns, have historically driven most major chemical risk policies. As a result, there appears to have been a greater emphasis on developing criteria or 'benchmarks' for examining human safety issues. In contrast, few benchmarks (other than use of ratios comparing predicted concentrations against predicted no effect concentrations) have been established for environmental risks. This is in part because of the wide range of end points which require consideration, and also because greater reliance is often placed upon site-specific considerations and the professional judgement of the assessors (see also Pittinger *et al.*, 1998).

3.2.4 Sustainability and Other Decision Criteria

Sustainability and the sustainable use of chemicals is likely to form a background to most governments' decision making with regard to chemical risk management. Despite the fact that the term 'sustainable development' was first defined 1987 ago by the World Commission on Environment and Development report (*Our Common Future,* the so-called 'Brundtland Report'), there is still considerable debate as to what this concept means in practice.

The definition set out in the Brundtland Report is that sustainable development is:

> *development that meets the needs of the present without compromising the ability of future generations to meet their own needs*

The implication of this definition is that, unless decisions are taken in the present to address either potential irreversible effects or those which may have a 'significant' impact at an intergenerational level, future generations either may not have the ability to address such effects or may face considerable costs in so doing. Within a generation, sustainability also implies particular concern for the most disadvantaged in society.[6] These views were strengthened at the 1992 Earth Summit in Rio, where the vision of sustainable development was enshrined in Agenda 21 with the aim of providing a structure to the balancing of environmental, social and economic development objectives.

Extensive literature exists on the subject of sustainable development and how it should be interpreted, with many authors setting out general concepts and principles, and others suggesting indicators for measuring the degree to which it is being achieved.[7] From a regulatory analysis perspective, the concept of sustainability is perhaps best viewed as adopting objectives designed to achieve a sustained flow of economic, environmental and social benefits that will enhance the quality of life without reducing the long-term productive capacity of the resource base. The preferred regulatory measure (out of a set of alternatives) should then be that measure which best meets these objectives.

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6 Although this is highlighted in the Brundtland Report, concern for the most disadvantaged may be inconsistent with concern for future generations (Pearce, 1998).

7 See, for example, Hart Environmental, 1996, OECD, 1995, Pearce *et al.*, 1996, Schultink, 1992, UNEP, 1992, and WCED, 1987.

This view introduces questions about compensation and the tradeability of economic, environmental, social and other goods. On the one hand, it is argued that sustainability should be interpreted as permitting free trade of all goods and services as long as the total value across all goods and services is not diminished. On the other hand, it is argued that not all goods and services are tradeable, as there are certain economic, social, health and environmental considerations which must be preserved or protected.[8] With regard to chemical risk management, either concept concerning the degree to which different goods and services are tradeable can form the context for undertaking an SEA, although the use of certain analytical approaches such as cost-benefit analysis tends to assume a greater rather than lesser tradeability.

In addition to sustainability criteria, decision makers are likely to consider a range of other criteria as part of chemical risk management (and these would feature in a good quality appraisal). Box 3(b) lists the decision criteria considered by Environment Canada to be relevant to chemical risk management (Environment Canada, 1994).

8 For further discussion of different sustainability concepts, see Pearce *et al.*, 1996, Rennings and Wiggering, 1997, and van den Bergh, 1996.

Box 3(b): Wider Considerations in Chemical Risk Management

Wider decision criteria noted by Environment Canada include:

- competitiveness implications: to what degree will a measure minimise the financial burden to industry, and what will the impact on international competitiveness be?
- incentives: does the measure directly or indirectly stimulate creativity and innovation through some form of incentive to develop and implement cleaner technologies and ways of operation?
- enforceability and compliance: how easy will it be to enforce and monitor compliance with this measure?
- growth: can the measure be structured in such a way as to allow for economic growth (for example, the entry of new producers into an industry) while still meeting environmental requirements and policy commitments?
- speed: how quickly will the environmental objectives be reached through this measure?
- fairness: does this measure impose an unfair burden on certain individuals/sectors in the market?
- intrusiveness and flexibility: what level of regulatory knowledge and involvement will be required to effectively apply this tool? To what extent does this tool leave to producers and consumers the specific detailed decisions about how to achieve environmental objectives?
- data requirements: what will be the data requirements for implementation of this measure in terms of quality, intensiveness and availability?
- compatibility: will the application of this measure support or be in conflict with established jurisdictional responsibilities, existing regulations or other initiatives?
- public acceptability: will the use of this tool for environmental management be readily accepted by the public?

Source: Environment Canada (1994)

3.3 Key Steps in the Analysis

Figure 3.1 provides a generalised framework outlining the role SEA can play in the overall process of decision making on chemical risk management. This example framework has four key steps:

- Step 1: Identifying the Potential Problem - this step relates to a risk issue entering the decision making agenda, and the factors which give rise to the need to consider risk management (for example, as a result of risk characterisation in terms of the potential acceptability or unacceptability of the level of risk);

- Step 2: Setting up the SEA - the objectives of risk management are elaborated in the second step, which also entails identification and involvement of the relevant stakeholders in the SEA;

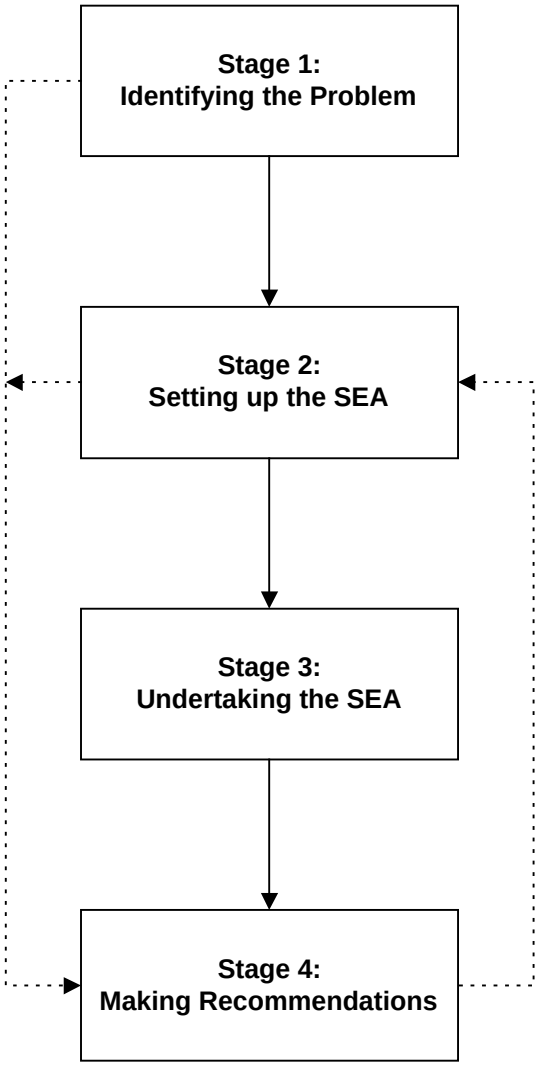
- Step 3: Undertaking the SEA - the analysis will require identification of alternative risk management measures, collation of data on the costs and benefits associated with the various alternatives, and assessment of predicted costs and benefits; again, this is likely to involve input from stakeholders; and

- Step 4: Making Recommendations - this final step includes the comparative analysis of the alternative measures, peer or expert review of analysis results, and involvement of stakeholders in order to provide a comprehensive set of recommendations to decision makers; this step also incorporates implementation of any decision and monitoring of its success.

The risk management framework presented in Figure 3.1 reflects the type of processes currently used in many OECD countries. The five-step approach to risk management set out in the EU's *Technical Guidance on Development of Risk Reduction Strategies*, under Regulation No. 793/93, is consistent with the process suggested here, as are the models used in the US for ecological risk management (Pittinger *et al.*, 1998).

However, the framework in Figure 3.1 is a simplified one. It does not highlight, for example, the need for ongoing dialogue between decision makers, risk assessors and socio-economic analysts. There will be several stages throughout the process where discussion among these parties is important to ensuring that the overall process is effective and that the decision maker's needs will be addressed.

Figure 3.1: Example Framework for SEA in Chemical Risk Management



3.4 Stage 1: Identifying the Potential Problem

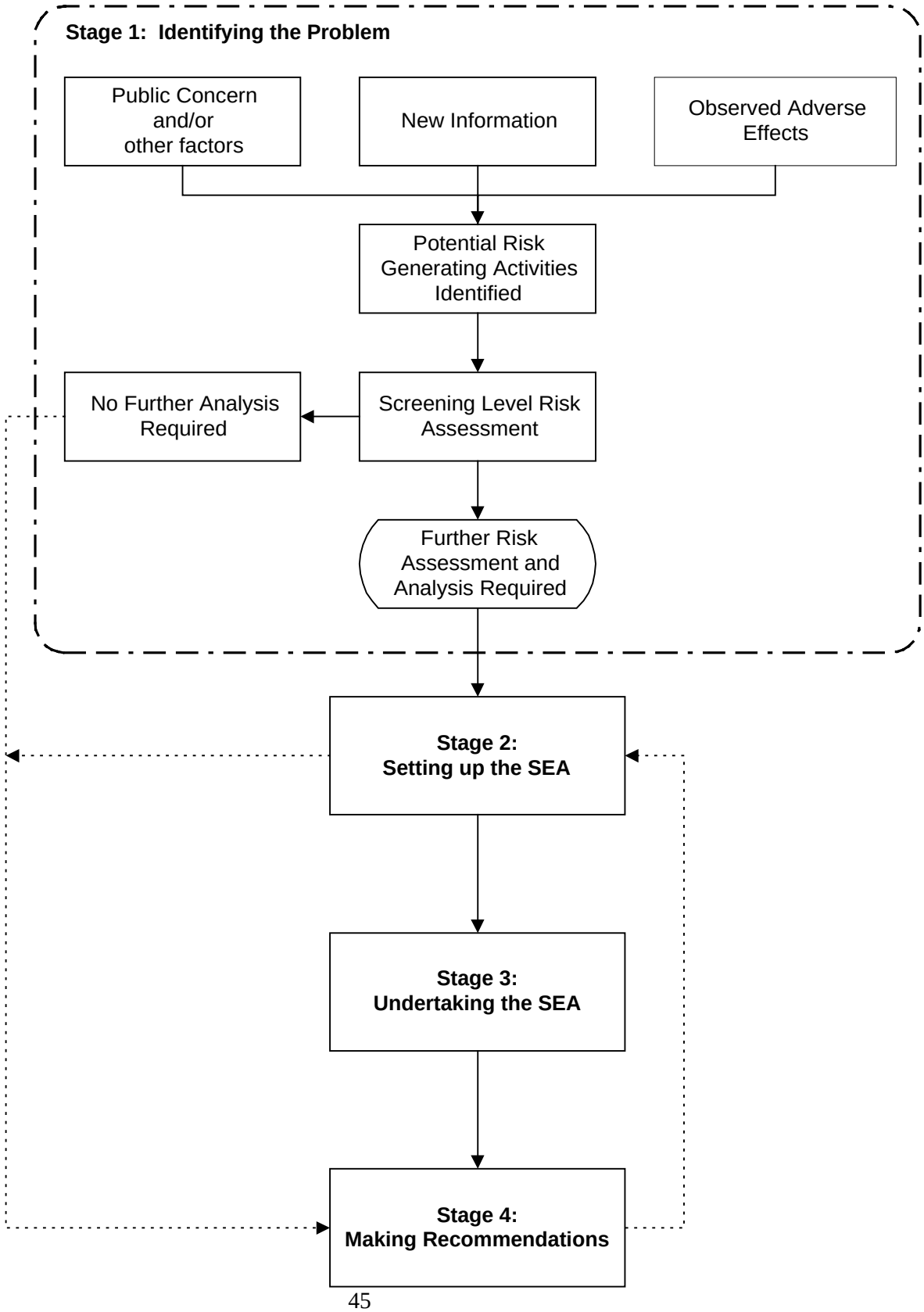
3.4.1 Overview

A risk issue may enter a decision maker's agenda through a number of different avenues: legislative requirements, government policy decisions, public concerns raised by the media, interest group pressure, the availability of new scientific information, or the availability of new technologies. How an issue arises is likely to affect the degree of urgency with which it is given attention and the way risk management itself is approached. The activities involved at this first stage include:

- identifying potential risk generating activities;
- undertaking a screening level risk assessment to determine if further, more detailed analysis is required; and
- where further analysis is required, preparing a fuller risk assessment (according to national and/or international requirements).

Figure 3.2 illustrates the relationship between these activities.

Figure 3.2: Identifying the Problem



3.4.2 Identifying Risk Generating Activities

In order to prepare either a screening level or more detailed risk assessment, details are required on activities which may give rise to the potential risk, and on the manner in which the risk may arise. For example, the EC *Technical Guidance on Development of Risk Reduction Strategies* (1998) notes that risks can arise:

- during any or all stages of a chemical's life cycle, including manufacture and industrial use, distribution and storage, professional and domestic use and disposal;
- either directly from use of a substance, as a result of subsequent environmental distribution and/or transformation, or through exposure to the substance when incorporated in a finished product; and
- from both point and diffuse sources, and from either single or repeated exposures.

Not only is this information essential to preparing a risk assessment, it also provides a means of focusing the subsequent analyses and the decision making process. Where a risk assessment precedes an SEA (as will often be the case), it may provide an indication of potential risk management options or lead to other decisions regarding the appropriate approach to risk management. Where the risk assessment and SEA are conducted in parallel, the decision maker, risk analyst and socio-economic analyst may jointly develop options to be considered in both assessments.

3.4.3 Risk Assessment

The next step within this phase concerns the application of risk assessment techniques. It is suggested here that a screening level assessment be undertaken to determine whether the risk posed by a given chemical (or perhaps a particular application) is likely to be acceptable or unacceptable. Where the screening level assessment indicates that the risk is acceptable, recommendations to this effect can be made (proceeding to Step 4). Risks found to be potentially unacceptable are then subject to a more detailed given assessment.

Within the OECD, chemical risk management involves preparation of a national risk assessment and, based on the results, consideration of whether the risk is likely to be acceptable. Risks characterised as unacceptable are then given further consideration, often through SEA, to determine whether and how the risk could be reduced through management action. In addition to determining a national strategy, as appropriate, the national decision maker of an OECD country would consider whether action should also be taken by other countries. If OECD-wide action is deemed warranted, the national 'champion' may provide the risk assessment and SEA conclusions for the chemical or chemical application, for consideration as a risk reduction priority and hence as appropriate for action under the OECD Chemicals Programme.

Within the framework set out here, the risk assessment itself is not part of an SEA but rather provides information to the SEA. The risk assessment is necessary not only to determine the nature and level of risk, but also to identify activities giving rise to the risk, and thus where potential risk management strategies are likely to be effective. A robust risk analysis is a vital precursor to effective use of SEA. According to Morgenstern (1997), SEA 'only adds value when scientists have laid the groundwork by developing credible quantitative estimates of the underlying physical relationships.' Equally, where the underlying risk assessment is weak, the SEA will also be weak. Analysis of 12 examples of decision making on environmental and health regulations in the US

concluded that 'in several of the cases…the available scientific information was seriously inadequate to develop a comprehensive and robust [SEA]' (Morgenstern, 1997).

Procedures exist for preparing risk assessments in most OECD countries as part of the OECD national risk assessment programme described above. In some cases, procedures are dictated by international requirements. For example, within the EU, Directive 93/67/EEC lays down common principles for assessing and evaluating risks to human health and the environment posed by new substances. Regulation (EC) No. 1488/94 lays down similar principles for the risks posed by existing substances. The recommended approach to risk assessment is set down in *Technical Guidance Document in Support of Commission Directive 93/67/EC on Risk Assessment of New Notified Substances* and *Directive and Commission Regulation (EC) No. 1488/94 on Risk Assessment of Existing Substances*.

Under the EU procedures, risks are characterised by comparing effects with exposure and recommendations are made concerning the need for risk reduction or mitigation. The assessment process is designed to determine the risks associated with the 'reasonable worst-case scenario', the aim being to ensure that risks are not underestimated.[9] The results are expressed as a risk/hazard quotient. In other countries, for example Canada and the US, the aim of the risk assessment phase is to prepare a fully quantified consequence analysis, presented as the probability of a particular effect given a specified level of exposure.

Although the outputs of the risk assessment form critical inputs to an SEA, they often do not include the type of risk information needed by the analysts undertaking the SEA. This was highlighted as an issue in the recent report by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1996), which recommended greater co-ordination between risk assessors and economists. Particular issues include that:

- a risk assessment may focus on only the most sensitive health end points, while an SEA requires information on all health effects;
- a risk assessment may report on margins of exposure without reporting the probability of an adverse health effect at different exposure levels;
- a risk assessment may report only information on risk to a highly exposed or maximally exposed individual, while the SEA requires information on the entire population risk distribution (i.e. the number of people or organisms experiencing various levels of exposure and risk).

Again, this highlights the need for an open dialogue between risk assessors and socio-economic analysts.

9 The selection of this scenario could lead in some cases to the expenditure of both private and public sector funds, beyond that needed for the prevention of unacceptable risks. This particularly applies in cases of great uncertainty, where the emphasis is on being precautionary.

3.5 Stage 2: Setting up the SEA

3.5.1 Overview

Once a decision has been made to proceed with an SEA, the next phase of work concerns establishing the framework for the analysis. This involves:

- defining the risk management objectives underlying the SEA;
- identifying the relevant stakeholders and how they are to be involved within the SEA process; and
- undertaking initial data collection to allow a screening of options and a focusing of the Stage 3 analysis; and
- developing specifications for the more detailed SEA.

Figure 3.3 illustrates the links between these activities.

3.5.2 Setting the Objectives

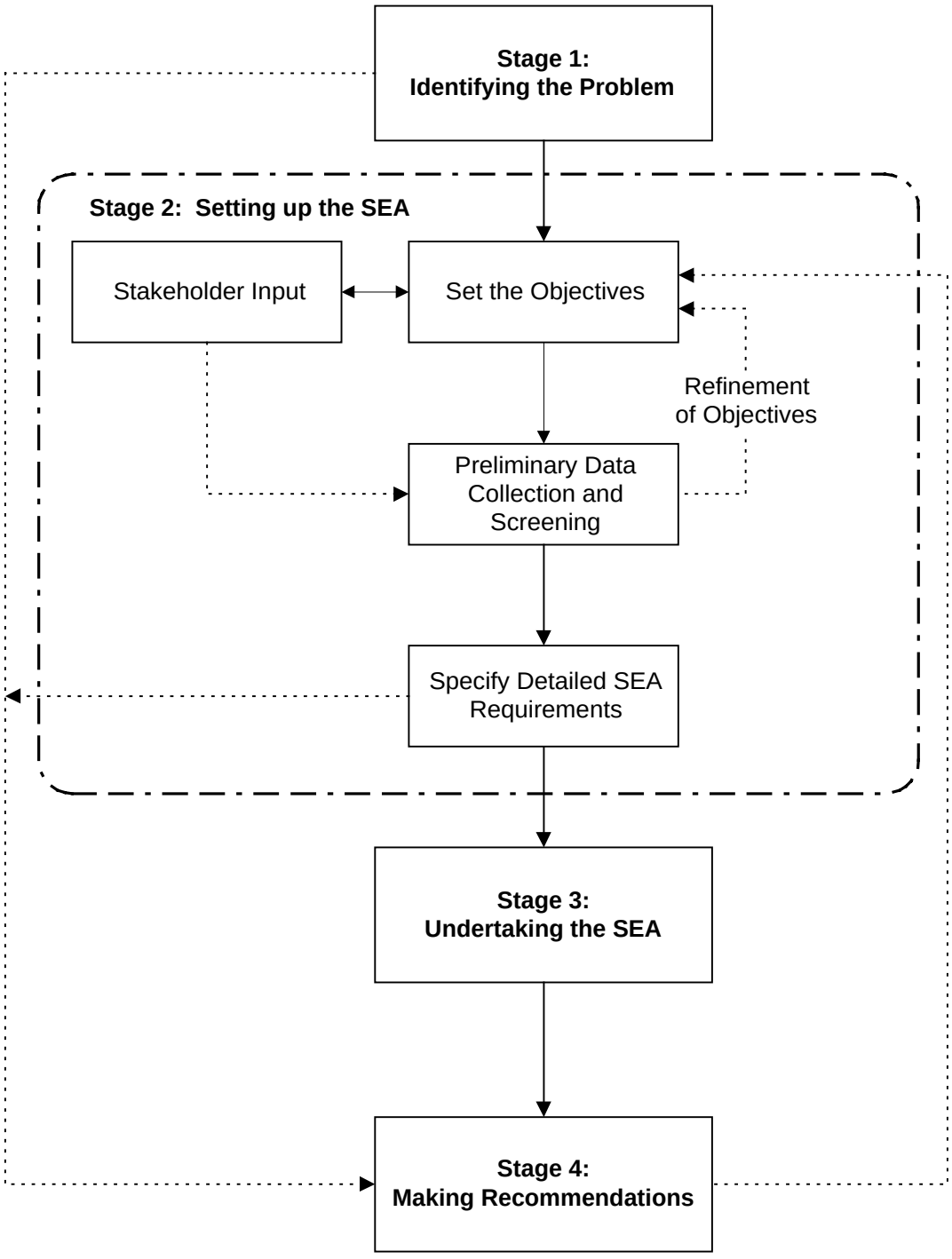
The outcome of the risk assessment will provide the basis for setting the objectives of the SEA. The objectives may be expanded or modified, however, depending on the nature of the overall analytical process adopted. It may be appropriate to define the objectives in general terms at the start of the analysis, refining them as more information becomes available. In general, the objectives should be established and stated in a manner which allows as much flexibility as possible when developing potential risk management options. In this regard, the objectives may also need to take into account any broader policy or programme objectives. In all cases, they should accurately state the intentions or commitment of the commissioning agency (and the end decision makers) and reflect stakeholder concerns and the level of agreement between all stakeholders regarding the objectives. Overall, they should instruct the scope of the SEA.

Thus, the way the objectives are defined is vital to the success of the SEA. The UK Health and Safety Executive and the UK Treasury suggest that objectives should be SMART (HSE, 1995):

- Specific;
- Measurable;
- Agreed;
- Realistic; and
- Time-dependent.

Similarly, Environment Canada and Health Canada have established an Options Evaluation Process for CEPA toxic substances which involves stakeholders in establishing the objectives and agenda for the SEA. This is achieved by developing an ‘Issue Table’ which sets the overall agenda for the analysis, the environmental and health objectives, and a time frame for achieving them within a sustainable development context. The aim is to develop an overall work plan for the SEA so as to ensure that the scientific, technical and socio-economic data necessary for the analysis are available.

Figure 3.3: Setting up the SEA



3.5.3 Identifying and Involving Stakeholders

As recognised by the Options Evaluation Process in Canada, any decision on chemical risk management is likely to affect a wide range of stakeholders. Some stakeholders, for example industry, may face significant costs as a result of a risk management decision, while the benefits may be distributed more widely across several different stakeholder groups. Often different stakeholders will have very different views on the acceptability of risks and the value of benefits arising from a decision. By involving stakeholders in the decision making process, the process itself becomes more accurate, more transparent, and potentially less contentious.

As well as the affected industry sectors, stakeholders are likely to include government departments (potentially at both federal and provincial/state level), industry, organised labour and workers, environmental organisations, other non-governmental organisations (such as consumer groups), and representatives of any ethnic or cultural interests that may be affected.

As the SEA provides a key basis for decision making, it is also important that stakeholders understand and, as far as possible, participate in the SEA process. A number of countries (Australia, Canada, the Netherlands, the US and the Nordic countries) place significant emphasis on the involvement of stakeholders from the early stages of the SEA process. The aim is to ensure the robustness of the SEA and improve its accuracy and transparency. It may also reduce the potential for conflict by incorporating the views of relevant groups or individuals.

Canada's Regulatory Policy of 1995 requires all regulatory authorities to 'ensure that Canadians are consulted, and that they have the opportunity to participate in developing or modifying regulations or regulatory programmes.' The effectiveness of this policy, and the performance of regulatory authorities in relation to it, is monitored by the Treasury Board Secretariat. In addition, Health Canada and Environment Canada allow for extensive stakeholder involvement within the Options Evaluation Process, in which public participation is a key principle. Industry, aboriginal groups and non-governmental organisations are the key stakeholders included in the Options Evaluation Process. Similarly, the Australian Environmental and Health Impact Assessment process stresses the importance of stakeholder involvement throughout the entire analysis process.

In Europe, the Netherlands' Ministry of Finance has adopted similar open appraisal procedures to allow for extensive consultation, although there is no formal requirement for this. The Austrian Federal Ministry for Environment, Youth and the Family involves stakeholders by consulting with other departments and agencies, as well as non-governmental environmental organisations. The Department of Environment, Transport and the Regions (DETR) in the UK has a similar approach. For example, in the development of DETR water policy, advisory groups are formed which consist of government departments and external interest groups. In other areas, the involvement is more informal, based on information-sharing between government and stakeholders. In Finland, specialist advisory committees, with representatives from government, industry, trade associations and labour organisations, are commonly used to support decision making. The Danish Government takes a slightly different approach to stakeholder involvement, relying on a 1,500 strong business panel to consult on the impacts of regulation. The panel is co-ordinated by an agency within the government's Trade and Industry Department.

Although the deliberate involvement of stakeholders should lead to better risk management decisions, a number of barriers to the effective involvement of stakeholders exist (Pittinger *et al.*, 1998):

- determining who the stakeholders are and the appropriate extent and type of involvement,

as this may vary from step to step and from one decision to another;

- difficulty in involving stakeholders beyond activists and pressure groups; in addition, many stakeholder groups lack sufficient expertise in SEA to make technically rigorous contributions to decision making (indicating the need for better risk communication with the lay public);

- problems in building partnerships between the public and private sectors, especially where issues of commercial confidentiality arise; and

- ensuring that stakeholder representatives are involved at national, regional and, where appropriate, international level.

The timing of stakeholder involvement is a critical factor in determining whether stakeholders can actually participate in the policy making process, and to what extent. Non-governmental organisations, for example, may meet only infrequently, and therefore a short timescale will limit their ability to participate. Other stakeholders may not be represented by established groups, limiting their capacity to participate. Similarly, the limited resources available to certain stakeholders, and/or a lack of scientific understanding, may restrict the role they can play.

In recognition of these difficulties, a number of governmental bodies in Europe and North America have focused on capacity-building among stakeholder groups, experimenting with novel approaches to participation such as citizens' juries, consensus conferencing, issue forums, study circles and citizens' panels. Such approaches do, however, require a reasonable timescale to develop.[10]

3.5.4 Identification of Options

Historically, there has been a tendency to adopt a regulatory approach to reduce or minimise chemical risks in which only one option for action is considered. In these cases, the role of SEA is simply to evaluate the advantages and disadvantages of the proposed control in order to help decide whether it should go ahead. The trend is changing, however, and there is increasing recognition of the need for more flexible approaches to risk management. A range of options which could meet the risk management objectives are likely to exist; in this case, the role of SEA is to help determine which of the options will bring the greatest overall benefits.

The aim of these more flexible approaches is not only to reduce costs to industry and consumers, but also to take advantage of the opportunities for further environmental improvement offered by some regulatory tools. At this stage of the assessment it is vital that the full range of potential regulatory tools are considered, so as to avoid premature rejection of viable options. Potential tools are:

- voluntary approaches, such as product stewardship and/or environmentally friendly product design;

- employee health and safety programmes;

10 For further discussion of stakeholder and participatory approaches, see National Research Council, 1996, for an American perspective and Renn, 1998, for a more European perspective.

- information tools, such as classification and labelling, or risk communication programmes;

- market based tools such as emission/effluent charges, product taxes, tradeable permit systems, and subsidies aimed at shifting producer, user and/or consumer behaviour; and

- command and control tools, such as marketing and use measures, emission or discharge limits, best available technology requirements.

Four separate lists of some 50 potential measures are included in the EC's *Technical Guidance on Development of Risk Reduction Strategies* (EC, 1998). Each list identifies potential measures for controlling risks arising from exposure during different stages of a chemical's life cycle. The Guidance recognises that the level of risk posed by a particular chemical will depend on a range of factors including its hazard potential, the nature of its use (or uses) and the degree of exposure which results from that use. Therefore, it also recognises the importance of ensuring that risk management activities are correctly targeted, which in many cases will require addressing risks associated with particular applications of a chemical rather than the use of the chemical in its entirety.

This latter aspect of the EC Guidance is important. Chemical risk reduction priorities are frequently identified in response to general information on potential environmental or health impacts, and/or in response to public perceptions of a risk. As a result, the starting point for governments may be to focus initially on the use of a chemical in its entirety (i.e. banning the chemical). Focusing risk management activities at this level, however, may fail to acknowledge differences in the risks and economic benefits associated with specific applications. Looking instead at the chemical application level should help ensure that risk reduction measures are properly targeted and that an appropriate balance is achieved between risks, costs and benefits. It should also help gain industry co-operation in working with government to identify the most appropriate risk management measures.

For any given chemical, therefore, several measures could be combined to form the basis for a risk management strategy, or one single measure may be sufficient. Implementation of some measures may require regulatory action, while industry can be the driving force behind others. For example, increasing emphasis is being placed on the role voluntary agreements can play at both a national and international level in achieving chemical risk reductions.

Examples of the role which voluntary actions can play at a national level in reducing high risk industrial chemicals are given by the US EPA's 33/50 programme and Canada's Accelerated Reduction/Elimination of Toxic Substances Programme (Carra, 1997). At a broader international level, the EC has published recommendations on the development and implementation of Environmental Agreements aimed at furthering the use of voluntary agreements and ensuring that they are effective (COM(96) 561 Final and OJ No. L333/59, 21.12.1996). The ability to develop and agree voluntary measures should not, however, be used as justification for failing to undertake an SEA. Efforts should still be made to determine whether the benefits of the proposed measures would justify their costs. Although such analyses have rarely been undertaken in the past, they are important to ensuring that resources (in this case industry's) are used effectively.

3.5.5 Preliminary Data Collection and Screening

Once the range of potential risk management options have been collected, the next step is to collect preliminary data on each of the options to enable a simple screening exercise to take place

(an overview of the tools which can assist in this step is provided in Section 4). The aim here is to undertake a preliminary comparison of cost, risk and benefit trade-offs, so as to reduce the number of options considered in the more detailed SEA.

Data on the manner in which a chemical is used and the activities within its life cycle that give rise to the risks of concern will be provided by the risk assessment. In addition, the risk assessment will provide an indication of the quantity of the chemical of concern used by each of the activities of concern. This information provides a backdrop to the screening process. Additional data requirements at this stage will include a rough indication (at least) of:

- the potential magnitude of costs to industry and consumers;
- the ability of the option to reduce risks and hence provide the desired benefits;
- the technical (and perhaps political) feasibility of the option;
- the potential for the option to give rise to new or increased health or environmental risks, or conversely to generate indirect benefits; and
- any administrative and other regulatory implications (monitoring, enforcement, legal) for both industry and government.

Obviously, criteria related to other factors could also be used as part of any screening exercise. However, it should be remembered that the aim at this stage is to highlight the degree to which the impacts of adopting the different tools are likely to vary significantly, and the degree to which some outperform others across all of the above criteria. Options which are viable and perform better than others with regard to at least one important criterion should not be eliminated at this stage, but should be carried forward to the next stage.

3.5.6 Specifying the Detailed SEA

The outcome of the screening exercise will provide valuable information for review by decision makers, the socio-economic analyst and other stakeholders. It should provide the basis for determining what is required of any more detailed assessment (although there should also be the potential for making recommendations on the basis of the screening results, taking into account the limited reliability of such exercises). In this regard, the exercise should inform:

- any refinements to the objectives of the SEA;
- the manner in which stakeholders are involved in the next stage, where this includes consideration of both who and how;
- the selection of the appraisal methodology to provide the basis for the analysis;
- the timing of key deliverables from the analysis;
- any key issues which may need to be given extra attention within the analysis.

3.6 Stage 3: Undertaking the SEA

3.6.1 Overview

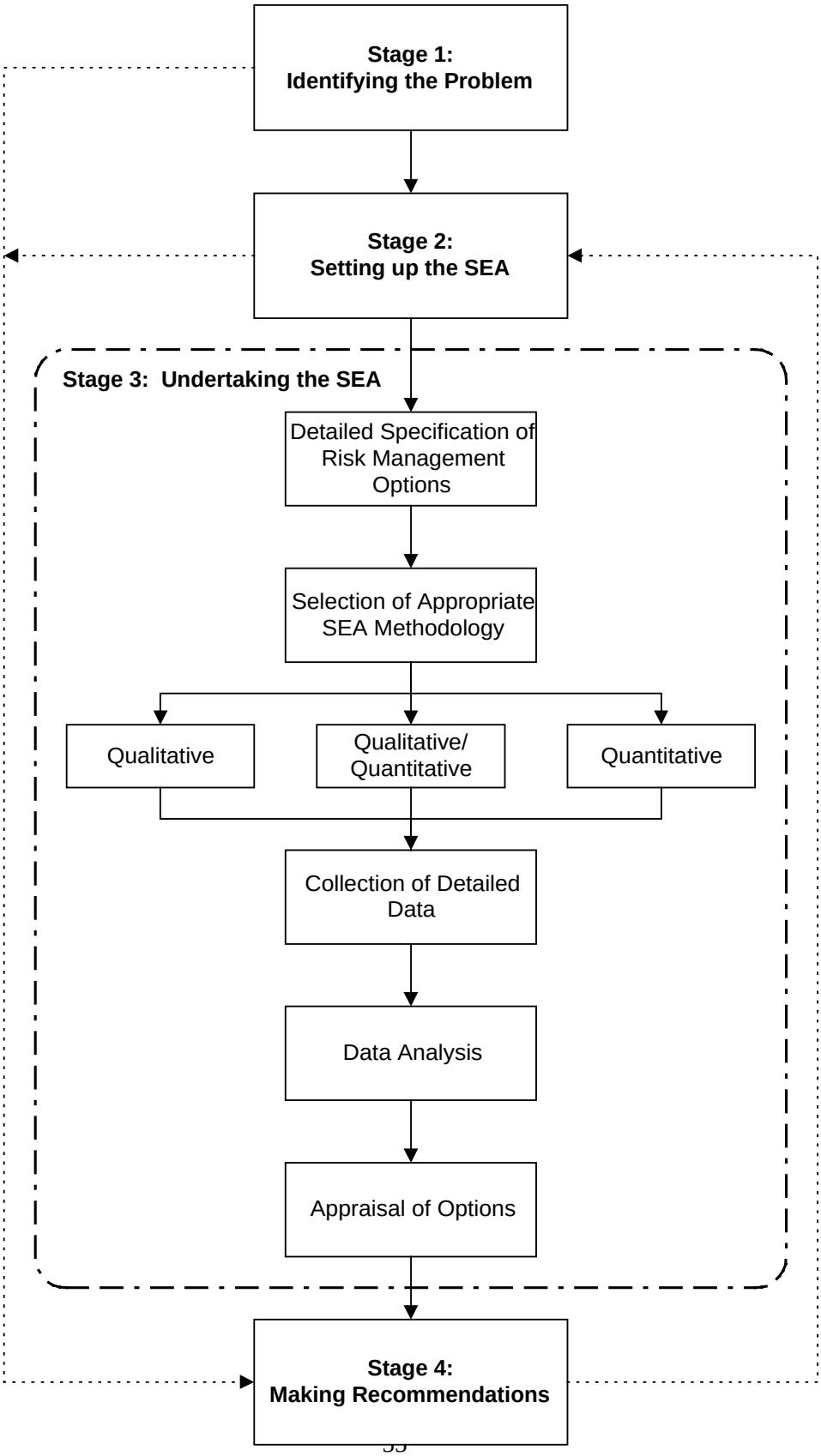
The third stage within the overall process comprises the more detailed SEA, including:

- detailed specification of the key risk management options;
- selection of the appraisal methodology(ies) to be used within the SEA;
- further data collection activities;

- analysis of the data; and
- comparative appraisal of the options.

Each of these components is considered briefly below, with Figure 3.4 indicating their relationships.

Figure 3.4: Undertaking the SEA



3.6.2 Identification of Key Risk Management Options

As noted in the previous section, there has been a tendency to consider only one option for some chemical risk management decisions. The aim of the screening exercise carried out as part of Stage 2 was to provide a mechanism for considering a fuller list of options at the start, yet also enabling this list to be reduced to a more manageable number for detailed analysis. It is important, however, that a set of alternative options is considered in detail; it is often argued that the failure to consider a range of different options is equivalent to doing 'bad' analysis. By way of example, Box 3(c) describes the potential role of alternative risk reduction measures in two examples of chemical risk management.

Prior to subjecting the refined set of options to detailed analysis, it is important to ensure that they are well defined and that key parameters which will affect the assessment of costs, risks and benefits are understood. For example, it may be necessary to specify parameters such as the timing of different events, the risk generating activities that would be affected, any sub-options available in terms of how a measure could be implemented, any restrictions which would be placed on the way the risk generators responded to a measure, etc.

Box 3(c): The Potential Role of Alternative Risk Reduction Measures

Economic Impact Analysis of Regulatory Options for the Dry Cleaning Sector

In a CBA undertaken by Environment Canada, costs and benefits were assessed for four possible options that could be used to control the use and release of perchloroethylene (perc) by dry cleaners. These options were:

a) mandatory technology regulation;
b) a quota on imports of perc;
c) a levy on importers and distributors of perc, and a subsidy to dry cleaners; and
d) a combined mandatory technology and levy/subsidy option.

The CBA indicated that, in the case of toxic materials use by small businesses, the implementation of an economic instrument such as a levy could be beneficial by minimising cost impacts on the regulated sector as well as limiting administration costs. Based on this analysis, discussions are underway regarding the implementation of a levy at a national level, while the Province of Quebec announced in its 1997 budget an intent to implement a levy/subsidy scheme for the dry cleaning industry.

Voluntary Commitments on Brominated Flame Retardants

Brominated flame retardants are applied to furniture, plastic-containing appliances and textiles to prevent or minimise the risk of fire. Following concern over emissions from retardants over their life cycle, the major global producers of brominated flame retardants have committed themselves to take actions to reduce the risks posed during their manufacture and disposal. These actions include commitments not to manufacture or import certain BFRs, use of best available techniques to improve the purity of others, and minimising levels of releases during manufacture. Industry committed itself to report on progress to the OECD's policy body on chemical safety in 1998 and every two years thereafter. If reports do not indicate that sufficient progress is being made to reduce potential risks, national governments may consider other actions.

Sources: Environment Canada, personal communication (1998); OECD (1997)

The aim in specifying these details is not to reduce the flexibility open to industry or others in responding to a proposed measure. Instead, it is hoped that specifying such parameters at the start of the detailed analysis will help ensure that everyone involved in the appraisal has a shared understanding of what different options would entail. This should help not only in data collection, but also in identifying possible variations in options which may have different cost, risk or benefit outcomes.

3.6.3 Selecting the SEA Methodology

In selecting the methodology which will provide the basis for the SEA, a number of factors should be considered:

- the stated objectives of the SEA and the requirements of decision makers with regard to having quantitative versus qualitative information (with these sometimes set by the relevant regulation);
- the number of costs and benefits of concern, and whether any specific health or environmental targets or thresholds have to be met for an option to be acceptable;
- the nature of the information available from the risk assessment (whether a full consequence analysis or more limited information on hazard or risk potential); and
- the period of time and resources (staff and money) available to the analyst.

These types of factors are also identified by the EC as important to the decision on the appropriate approach to the analysis. For example, Box 3(d) indicates the factors suggested in the *Technical Guidance on Development of Risk Reduction Strategies* (EC, 1998) that should be taken into account when determining the form an SEA should take.

Box 3(d): Factors in Determining form of SEA

Directorate General XI of the European Commission in its Guidance on developing risk reduction strategies suggests that the form of any analysis, whether qualitative or quantitative, should consider factors such as:

- the severity and extent of the risk;
- the scale of the drawbacks;
- the balance between the likely advantages and drawbacks;
- the information available within a reasonable cost and a reasonable time frame; and
- the level of uncertainty surrounding the likely advantages and drawbacks.

Source: European Commission (1998)

In general, the greater the complexity of issues requiring examination, and the more quantitative the analysis is to be, the greater the elapsed time and level of resources required to undertake an SEA. The lower the level of quantification required (for example, where a target has been set or the risk assessment limits the degree of quantification) and the less complex the issues of concern

are, the lower the level of resources required to complete the analysis. There will of course be exceptions to this general rule.

Of key importance is the need to recognise the multi-faceted nature of the decisions that will have to be made using the results of the analysis. A wide range of different issues need to be taken into account, stemming in part from the varying interests of the stakeholders, which in turn lead to varying priorities for risk management. For industry stakeholders, achieving effective risk management at a minimum cost will be a priority, while for others the priority may be to reach desired levels of environmental quality or worker safety regardless of costs. As a result, methods which assist in identifying the trade-offs between the various criteria are likely to be essential for most decisions. The method applied to a particular risk management problem, however, will depend upon the characteristics of the problem noted above and the extent of the differences in position among the stakeholder groups.

Depending on the requirements, an SEA may take one of three possible forms:

- a systematic qualitative analysis, where the magnitude, significance and relative importance of the risks, costs and benefits are described but not quantified;

- a semi-quantitative analysis, where some aspects of the risks, costs and benefits are assessed in quantitative terms while others are treated qualitatively; or

- a fully quantitative analysis, where all risks, costs and benefits are quantified in physical/natural units and/or, in some cases, in monetary terms.

A *qualitative* analysis will generally be sufficient where there are readily affordable solutions and there is common agreement that risk management is required. In other cases, a qualitative analysis may not be sufficiently detailed to show whether the benefits from risk management outweigh the costs. As a result, a more quantitative analysis is likely to be required, with this taking the form of either a semi-quantitative or a fully quantitative analysis. However, the potential savings, and greater assurance of meeting decision makers' and stakeholders' objectives through making a more informed decision, should justify the cost of undertaking a more quantitative analysis.

In general, the more *quantitative* the approach, the more informative the analysis is likely to be, but also the more resource-intensive. Any analysis will inevitably involve management of uncertainty and will require informed, professional judgements to be made. As a result, achieving a balance between the thoroughness of the analysis and practical limits to carrying out an analysis will be essential (Office of Management and Budget, 1996). In considering where such a balance lies, it is interesting to note the conclusions of a study reviewing SEAs of 12 proposed US regulations (Morgenstern, 1997). This study concluded that 'Given the modest one-time costs of these analyses compared to the annual costs of the [regulations] – over US $100 million – a reduction in costs or an increase in benefits of the final [regulation] of well under one percent – probably closer to one-tenth of one percent – could easily justify the cost of an economic analysis.' On this basis, the benefit of improved regulation 'clearly outweighs' the one-time cost of carrying out the analysis. The costs of SEA in the examples covered by the study ranged from US $180,000 to $8 million.

A study undertaken for the Nordic Council of Ministers (Hokkanen and Pellinen, 1997) promotes a stepped approach to SEA, starting with the application of qualitative assessment techniques. Semi-quantitative or more fully quantitative techniques are then applied as warranted by the magnitude of the trade-offs involved in selecting one course of action over another. The study goes further, to suggest that, given the complexity of the decisions and the number of factors that need to be taken

into account, for many risk management problems the combined use of a number of techniques may prove the most valuable.

Table 3.5 provides an overview of the main semi-/fully quantitative methodological frameworks which can provide the basis for the SEA: CEA, CBA and MCA. These key methodologies, together with other widely used (and often complementary) approaches, are discussed in more detail in Section 4, which provides a summary of what is involved in their application. In general, the principles underlying CBA appear to provide the preferred framework for many countries which currently have established programmes involving the application of SEA to chemical risk management.

3.6.4 Detailed Data Collection

The methodology to be used in preparing the SEA will, to a large extent, determine the type and form (whether qualitative, quantified in physical terms, or related to monetary values) of the data required at this stage. In many cases, a wide range of data are likely to be required in order to provide the detail and comprehensive coverage of the issues desired by stakeholders and decision makers.

A review of current guidelines indicates that the following types of data are generally considered important:

- information on the number of companies using a substance, levels of use, and expected trends in use;
- details of the implications of the proposed measure in terms of any changes required to existing processes (technologies used, chemicals used, level of treatment, etc.), reporting, monitoring, enforcement or other requirements;
- data on the capital and/or recurrent costs (and/or savings) associated with the introduction of a proposed measure;
- information on rates of, and potential for, technological change in the sector of concern;
- impacts on trade and the competitiveness of industry;
- impacts to small and medium-sized enterprises;
- impacts on consumers in terms of increased product prices, changes in the quality of end products, reduced availability of particular products, etc.;
- predictions of the benefits in terms of reduced impacts on human health and the environment associated with the reduced or more controlled use of the chemical in question, and also of any increased risks arising from the proposed measure - for example, where it leads to the adoption of a substitute chemical, or where increased effluent treatment leads to a shift in risks from the aquatic environment to the terrestrial environment from higher concentrations in sludge applied to land;
- any wider implications of a proposed measure in terms of its impacts on employment, other industrial sectors, etc. and thus the economy more generally.

Table 3.5: Key Aspects of the Quantitative Appraisal Methodologies				
Methodology	**Principles**	**Qualitative vs. quantitative data**	**Advantages**	**Disadvantages**
Cost-effectiveness analysis	Based on principles of economic appraisal, but the aim is to find the least-cost method of achieving standards.	Only costs are usually estimated in money terms. Where targets are set, these are usually quantitative, but other effects may be assessed either qualitatively or quantitatively.	Allows selection of the lowest-cost alternative to achieve pre-set level of protection. Often used when benefit measures cannot be monetised.	Provides less information than CBA on the most efficient level of control. Unlike CBA, does not provide information on whether the benefits gained by an action will be greater than the costs of adopting that action. Thus, alternatives that ensure positive net benefits cannot be identified.
Cost-benefit analysis (or risk-benefit analysis)	Based on principles of welfare economics. Assumes that society's values are reflected in individuals' willingness to pay.	Analysis may contain qualitative, quantitative (quantified but not necessarily monetised) or fully monetised information. Rarely will it be possible to value all impacts.	Use of familiar and common unit of measure. Provides information on whether the benefits of an action outweigh the costs, and the level of risk reduction which provides for the greatest level of benefits over costs. Allows direct comparison of regulatory decisions.	Monetary valuation of all costs and benefits is likely to be costly. Some question the validity and reliability of such valuations.
Multi-criteria techniques	The more complex techniques have a basis in utility theory; simpler methods stem from the need to convey information in a readily accessible form.	Can assess impacts using either qualitative or quantitative indicators of effect and significance.	Multi-attribute nature of problem is respected. Allows distinction to be made between impact and importance of impact to decision.	Difficulties in defining agreed scoring and weighting systems. Problems with double counting in some past applications. Aggregation to a single unit of measure (or a small number of indicators) is meaningless outside specific study.

For any particular assessment, some of the above data may not be available either because they do not exist or because they are not readily accessible to the analyst. In the latter case, the involvement of stakeholders from an early stage in the SEA may be vital in providing increased access to any data that they hold.

It does not necessarily follow, however, that the ready availability of extensive quantities of data means a highly detailed analysis should be carried out. Instead, the level of detail should be determined by the nature of the problem and the extent of resources required to make the desired improvement. For example, where the potential impacts of a decision are limited to minor increases in costs to one sector of industry, will have no impact on consumers, or will not give rise to any new risks to the environment or health, a more simple analysis may suffice. More detailed and comprehensive appraisals would be needed where there are significant trade-offs between the costs, risks and benefits of the measure, for example where a measure is likely to have significant cost implications for a large number of industry sectors and consumers and there are health versus environment trade-offs.

Many countries also require details on the distributional effects of a proposed measure in terms of ensuring that those gaining and losing from a particular risk management measure are identified. In this regard, distributional issues consider not only impacts across different industry sectors and sizes of companies affected, but also across other stakeholder groups. For example, concern has arisen in a number of countries, most notably Australia, Canada, New Zealand and the US, over the need to ensure that cultural and other socio-economic differences are taken into account where proposed measures would impact differentially on particular groups within society. In the US, concern over the 'environmental justice' of new or modified regulations has led to the requirement for such issues to be specifically addressed in regulatory appraisals (see also Section 7.5). The aim is to help ensure that any significant equity considerations are brought into the decision making process, including possible impacts on future generations (inter-generational equity). Such considerations can either directly incorporated into the SEA (through the use of MCA based distributional weighting techniques) or be provided as additional information to the analysis. The appropriateness of the different approaches is currently the focus of a US EPA task force looking into consistency issues within SEA.

3.6.5 Data Analysis and Appraisal of Options

For most regulatory issues it should be possible to develop estimates of the costs involved in adopting and implementing a risk management option. Similarly, many of the financial benefits to producers and other stakeholders associated with use of a chemical or activity may be readily calculated. Risk assessment techniques can provide information on the change in risks. Such data will be relevant to all analyses.

However, the methodological framework chosen for the SEA will determine the manner in which the data are analysed, and thus the manner in which the alternative options are comparatively assessed. For example, in those cases where CBA provides the framework and data are available on the probability of risk outcomes, it may be possible to place a monetary value on the level of risk reduction (although this will rarely be possible within the EU context, as the risk assessment approach does not normally produce probabilistic risk data). Where such valuation is feasible, expression of safety benefits in the same units (money) as the costs of control allows direct comparison of the trade-offs associated with alternative measures.

The manner in which different methodologies treat data, and thus allow for the comparison of options, is discussed in Section 4 for the key qualitative and quantitative assessment methods. It is important to emphasize here, however, that several analytical issues are common to all SEAs. The key issues highlighted in most guidelines are:

- specification of the baseline for the analysis, where this defines the levels and nature of chemical use in the absence of the risk management actions being proposed;
- specification of the time horizon over which predictions of likely impacts are to be made;
- the reliability of predictions concerning the likely magnitude of costs and benefits, with this being relevant to both qualitative and quantitative assessments;
- the explicit assessment of alternatives, and assumptions made concerning their availability, efficiency/efficacy and associated risks; and
- the management of uncertainty, whether scientific or value related within the analysis.

For those analyses which involve some degree of quantification and valuation of costs and/or benefits, an additional issue arises concerning the treatment of future streams of costs and benefits which are usually discounted to convert them into a single, present day estimate. This issue, and those listed above, are discussed in more detail in Section 7. The manner in which they are approached can be critical to the success and acceptability of an analysis.

3.7 Stage 4: Making Recommendations

3.7.1 The Role of the SEA

As the aim of SEA is to inform the decision making process, the final step requires information to be brought together in a form which assists decision makers in understanding trade-offs, and which provides the basis for communicating the information to the various stakeholders. This will focus discussion among stakeholders as to the merits of particular measures, and help develop a shared understanding of the implications of taking action (or not taking action).

As indicated in Figure 3.5, within this final stage several different activities are relevant:

- presentation of information in a useable format;
- peer review of the analysis results by either government reviewers or external experts; and
- formulating conclusions and, as appropriate, recommendations.

3.7.2 Presenting Information to Decision Makers

Decision makers, and those affected by decisions, need the key findings of the analysis to be presented in a clear and precise manner, stating assumptions, data sources and any uncertainties contained within them. It is essential, therefore, that the analysis and any conclusions reached are transparent. This will help ensure that the results are correctly interpreted, and also that users of the

results have confidence in them and are able to understand whether there are any significant gaps in the analysis.

Obviously, the manner in which the results of an SEA are reported will depend on the methodology which has formed the basis for the analysis. For all analyses, it will be important to provide a comprehensive overview of the analysis findings and to present a summary of the trade-offs associated with adopting one option over another.

One simple means of conveying information on trade-offs, which can be applied to the types of information generated by a qualitative assessment, CEA, CBA or MCA, is the use of matrices. A matrix such as that presented in Table 3.6 can convey comprehensive information on the trade-offs involved in selecting one option over another, including:

- the associated risks, benefits and costs for each option;
- the risks associated with the use of substitutes;
- the key parameters affecting the decision, key uncertainties, and the sensitivity of the end results to these; and
- the relative impacts across different control options.

The matrix in Table 3.6 provides an example of a highly simplified CEA, but contains the key elements of an effective presentation. Other presentational formats could easily be used to present much greater detail, spelling out effects for specific impact categories and actors within the chain of trade. Such an approach can help ensure that there is consistency in the way impacts assessed using qualitative indicators, in particular, are presented. The greater the level of detail, however, the greater the possibility that the matrix itself will become too unwieldy to achieve its aim of communicating information to decision makers in an efficient manner.

Figure 3.5: Making Recommendations

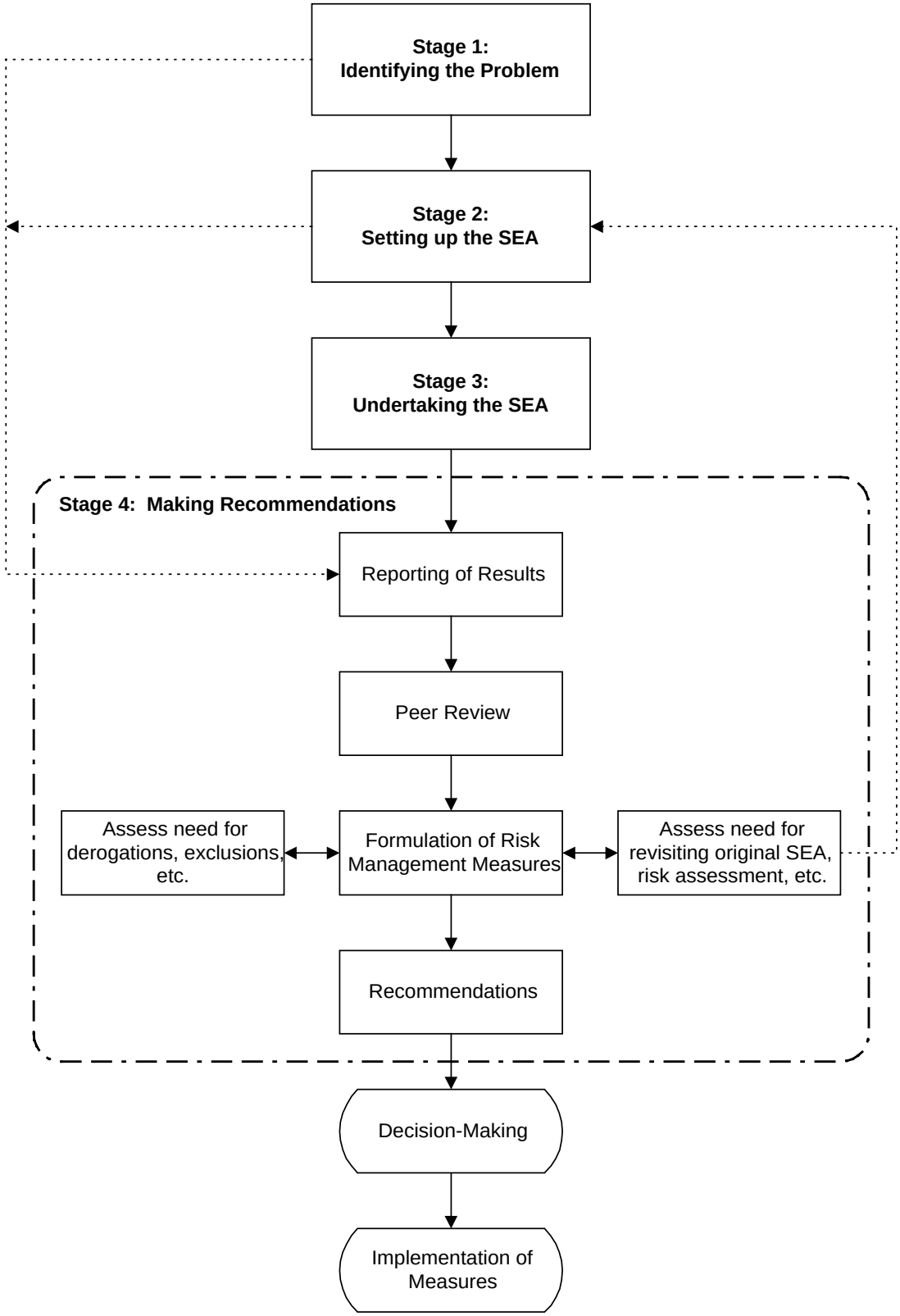


Table 3.6: Example of a SEA Results Summary			
Option	**Risks/benefits**	**Costs**	**Uncertainties**
A: Do-nothing	Current annual fatal cancer risk is estimated to be 10 per 10 million people per year.	None	Significant uncertainty associated with dose-response relationship
B: Ban X	Risks associated with X are eliminated, but annual fatal cancer risk associated with substitute Z is about 5 per 10 million people per year. The reduction in net annual fatal cancer risks is 5 per 10 million people per year.	$100 million per year	Costs to industry (particularly in relation to possible changes in product sales) are difficult to estimate. Risk determination is problematic, as it depends on how Z will be incorporated into product ranges.
C: Limit use of X in certain processes	Annual fatal cancer risks associated with X are reduced to 2 per 10 million people per year, but annual fatal cancer risk associated with substitute Z is about 4 per 10 million people per year. The reduction in net annual fatal cancer risks is 4 per 10 million people per year	$60 million per year	Risks associated with Z well documented. Many companies formulating X may go out of business (due to loss of profitable domestic market share) - hence costs highly uncertain.

3.7.3 Peer Review and Consultation

Peer review of SEAs is important to ensuring that the analysis is robust and will stand up to external scrutiny. The aim of a peer review is to validate both the data and assumptions used within an analysis, and the manner in which those data are analysed. As one might expect, the various countries which currently rely on the use of SEA depend on a number of different mechanisms as part of the peer review process. For example:

- other government agencies with specialists in particular fields (e.g. economics or eco-toxicology) may act as peer reviewers of either part or all of an analysis; and/or

- external specialists may be asked to peer review an analysis prior to its more public release.

A peer review is likely to be of value in cases where there are significant trade-offs involved in the choice of risk management option, or where new or novel methodologies have been used. In particular, when the costs of risk management are expected to be high and may have significant impacts on a particular industry sector, a number of sectors or the economy more generally, it is likely to be an important part of the process. In such cases, external reviewers should be selected so as to provide specific technical expertise relevant to the issues at hand. It will also be important to ensure that, when choosing reviewers, potential conflicts of interest are avoided (and where this is not possible, that a balance in interests is achieved). For further discussion on the value which a

peer review process can have in improving the credibility and quality of chemical risk management decisions, see Jasanoff, 1990, and Graham, 1991.

3.7.4 Formulating Risk Management Recommendations

The results of the SEA will form only one set of data, which will be taken into account by decision makers when determining the risk management option to be implemented. It therefore does not make the decision but informs it, as other factors will also be taken into account. Within this context, however, it may be appropriate for the SEA to make a number of different recommendations for consideration by decision makers (with what is considered appropriate obviously varying across different national and international decision making contexts).

Such recommendations may take many forms and should take into account any feedback provided by the peer review, or through a final consultation with stakeholders. For example, the SEA may (on the basis of the analysis findings) indicate which of the options considered appears to be the preferred one. Alternatively, the SEA may recommend:

- that measures are introduced, but that consideration is given to the potential need for exemptions or derogations in certain specified circumstances; for example, where specific activities or products would be particularly hard hit by a control, where the use of a chemical is part of a product specification which cannot be easily modified as a result of other legislation requirements (e.g. in the case of pharmaceutical goods), or where there are concerns that the risks posed by alternatives may be equal to or greater than those associated with the chemical application of concern;

- delaying any decision until the results of further studies become available, where this relates to further risk assessment data, further research on the risks of the alternatives, or further information on financial and economic impacts; or

- re-running the analysis to allow consideration of newly identified options which may provide a better balance of costs and benefits, for example by incorporating measures to ameliorate the financial impacts faced by particular sectors.

It may also be appropriate for the recommendations to touch on issues other than chemical control. For example, in cases where the public's perception of risks does not reflect actual risk levels, the conclusions may include suggestions on measures aimed at improving risk communication.

4. TOOLS FOR SOCIO-ECONOMIC ANALYSIS

4.1 Overview

The previous section set out a framework for informing risk management decision making and discussed the core set of activities specific to socio-economic analysis. It also acknowledged that the analysis itself may take a number of different forms, varying from a fully qualitative to a fully quantitative assessment, depending on factors such as the methodology adopted by the analyst, data availability, and time constraints.

The methodologies underlying most countries' approaches to SEA are based on the principles of economic appraisal as mentioned in Section 3.6.3. In particular, CBA and CEA form the basis for most chemical risk related socio-economic analyses, with multi-criteria analysis being used less frequently. Proponents of economic appraisal argue that this is because it provides a systematic framework for collecting and organising information. The template character of such analyses enables the decision maker to determine the adequacy of the information collected, to identify whether and what important information is missing, and to incorporate the conclusions into the risk management decision making process.

While CBA and CEA may be more commonly used or suggested for use within SEAs, the full range of tools is much wider and includes:

- simple screening and choice methods;
- abatement cost function analysis;
- financial analysis;
- cost-benefit analysis (CBA);
- cost-effectiveness analysis (CEA);
- input-output models (I-O);
- general equilibrium models (GE); and
- multi-criteria analysis (MCA - where this includes the range of scoring and weighting techniques).

A range of methods can be used as part of qualitative approaches to assist in the screening of options and in choosing between options. Such methods can be used as a first step within an SEA or complement the use of quantitative data, for example on costs. The development of abatement cost functions is often a first step to developing cost estimates, and this form of analysis can provide an input into wider financial and economic analyses. Financial analyses, CBA and CEA are effectively 'bottom-up' approaches, in that they consider the implications of adopting a measure at the micro, or individual action, level. They focus on estimating the direct effects of a proposed measure, although they may also capture many of the secondary or indirect effects which can result.

The next two forms of analysis (I-O and GE) provide 'top-down' approaches, in that they focus on the impacts of a proposed measure at a sectoral level and on the structure and functioning of the economy as a whole. These two approaches are less commonly used as part of chemical risk management, and are most relevant in cases where a measure would change the prices and costs faced by a large number of production activities (whether in private or public ownership).

It should be noted that the above forms of economic analysis are not exclusive in nature. There may be many cases where both bottom-up and top-down analyses will add valuable information to

decision making. This may be the case where regulations are likely to affect a chemical which is used by, or is a pollutant emission of, a highly integrated product or production process (such as a fuel or energy source). Examples of such regulations are given by some of the measures related to air quality and global warming which may impact on a group of specific industry sectors (such as large users of fossil fuels) and also on those market sectors supplying and buying from this group. In such cases, because a regulatory measure may have a widespread effect on the economy, it may be important to consider not only the direct effects of a measure on the target sectors, but also indirect or secondary effects on the economy more generally.

MCA is generally applied from a 'bottom-up' perspective, although some applications have been more 'top-down' in nature. It, too, can be used together with financial and economic analysis where full monetary valuation of social costs and benefits is not possible. In such cases, MCA may provide a valuable tool for assessing the relative performance of different regulatory measures against different objectives and impact criteria.

Brief reviews of all of the above forms of analysis are given below, with a number of sources providing more detailed discussion of their application in practice (see, for example, OECD, 1994, and OECD, 1997).

4.2 Simple Screening and Choice Methods

4.2.1 Screening Techniques

A range of methods have been developed to aid in the choice of options at a simple level, including screening, ranking and pairwise comparison techniques.

Screening methods are most likely to be used in the early stages of decision making to assist in narrowing down the options to be considered in more detailed assessments. Through screening, options are eliminated from further consideration on the basis of whether or not they meet particular criteria. The process can be based on:

- checklists of criteria which must be satisfied (e.g. related to levels of risk reduction, distribution and magnitude of impacts on industry, quality of end products, administrative simplicity, etc.); or

- specific minimum or maximum values which must be adhered to (e.g. should cost no more than a given sum of money per unit of risk reduction, should reduce environmental concentrations to a specific maximum).

Screening is also sometimes carried out across impact categories in cases where the difference between options is not relevant to the decision. For example, if none of the options has a significant effect for a given impact category, or if the effect is the same over all the options, screening is used to exclude the category from further analysis.

The aim of screening is to provide decision makers with a series of options, all of which are acceptable to a greater or lesser degree and which can be taken forward for further analysis or consideration. By applying these techniques, the weaknesses in particular options can be highlighted to allow their re-design or modification. In addition, the task of defining checklists and thresholds for acceptability can be a useful exercise in itself, as it forces decision makers to be explicit in defining their objectives.

There is a danger, however, that an option may be screened out on the basis of one criterion, the importance of which may be minimal in comparison to other decision criteria. Similarly, where the 'acceptable' threshold is represented by a specific value, an alternative may be excluded which fails by a very small margin to meet this value. For example, a maximum daily concentration of a contaminant in an effluent stream could be set at 100 µg/litre. This would mean that any option which resulted in a concentration of 101 µg/litre on only one or two days of the year could be excluded, even though it might result in lower annual average concentrations. Such potential problems could obviously be controlled by ensuring that some care and discrimination are employed before alternatives are eliminated from further consideration.

4.2.2 Ranking Methods

Ranking involves the ordering of options or impacts into ranks, using verbal, alphabetical or numerical scales, and provides an indication of relative performance. Value judgements (e.g. expert opinion or the decision maker's) are used to decide on the order of preference for different options or impacts. Thus, for example, if there were five options and a numerical scale were being used, the 'best' option would receive a ranking of 1 and the 'worst' a ranking of 5.

These methods obviously provide a simple method of evaluating the performance of different options over a range of different criteria. They may be of particular value where value judgements are required to determine the significance of different types of impact. However, when used on its own, ranking provides little information on the degree or magnitude of any differences in impact between options. It therefore hides any uncertainty which may exist as to the extent of such differences. In addition, when there are several options under consideration, it may be difficult to select a preferred option. This latter problem has led to the tendency for people to add ranks together, a mathematical operation which is invalid as ranking alone takes no account of the relative (or proportional) differences between the level of impacts.

There are a number of different approaches to ranking, such as the 'outranking method', which ranks the alternative options to identify the preferred option and the best and the worst of the available options, and 'positional analysis', which identifies the option which goes furthest towards minimising or maximising the most important criteria.

4.2.3 Pairwise Comparison Techniques

Pairwise comparisons and trend analysis provide alternative methods for identifying the preferred option.

The first stage in undertaking pairwise comparisons involves listing the criteria or impacts and comparing options in pairs against each of these, indicating a preference for one option over another. The results are then recorded in a table, such as Table 4.1, to illustrate which alternative performs better or worse for each of the criteria. An overall preference is then identified, or the information is used to highlight the trade-offs involved in selecting one option over another. The information is provided to decision makers, who must make a judgement on the relative importance to be assigned to the different criteria and thus to determine the 'best' option. Although this approach is readily applied to problems with only a few options or criteria, undertaking the comparisons and ensuring consistency becomes increasingly complex as the numbers of criteria and options increase. Applying pairwise comparison techniques in such cases can only effectively

be achieved through the use of the more sophisticated mathematical programmes which have been developed for these purposes.

Table 4.1: The Use of Pairwise Comparisons

Risk reduction measure	Health risks	Environ-mental risks	Costs to industry	Costs to regulator	Costs to consumers
A versus B	A>B	A=B	A<B	A=B	A<B
A versus C	A>C	A>C	A<C	A<C	A=C
B versus C	B>C	B>C	B>C	B<C	B<C

From the above comparisons, the preferred options are, in terms of:

- Health risks: Option C preferred, as it results in lowest level of risk: C<B<A
- Environmental risks: Option C preferred, as it results in lowest level of risk: C<A, B
- Costs to industry: Option A preferred, as it results in lowest costs to industry: A<C<B
- Costs to regulator: Option A or B preferred as both are equal and lower than C
- Costs to consumers: Options B preferred, as it results in lowest costs: B<A, C

Trend analysis provides a similar but alternative method of comparing options and can be used to provide quick indicators of the potential implications of a proposed regulation. Box 4(a) illustrates the type of table which may provide the basis for trend analysis as part of chemical risk management, to indicate the magnitude of predicted impacts for different criteria of concern (see also EC, 1997). As can be seen from this example, this type of analysis may be useful at a preliminary level to identify the potential impacts of a risk reduction measure (through initial consultation of stakeholders and a review of existing scientific and other data). Because it provides an instant overview of the key impacts, like screening techniques it may be quite valuable in communicating information to decision makers.

However, as with the other methods described above, trend analysis alone fails to provide an indication of the relative magnitude of the impacts across the different sectors: for example, whether the costs to industry and consumers are greater or less than human health and environmental benefits. Because of this, it would also be inappropriate to add the number of ticks together under each column (advantages, no effect, disadvantages) to compare the risk reduction measure presented here against one another. Such tables must, therefore, be backed up by further descriptive information if decision makers and others are to be provided with an accurate picture of the implications associated with alternative risk reduction measures.

Box 4(a): Trend Analysis of Advantages and Drawbacks of a Chemical Risk Reduction Option

A trend analysis as part of a preliminary analysis of a proposed risk reduction regulation could be structured in the following manner:

Key sector	**Advantages**	**No effect**	**Drawbacks**	**Comments**
Producers/manufacturers			•••	
Related industries			•	
Consumers			•	
Distributional issues		•		
Change in health risks	••			
Changes in environmental risks	••			

• Negligible impact
•• Medium impact
••• Large impact

4.3 Abatement Cost Function Analysis

Abatement cost function analysis has been described as the 'workhorse' of environmental economics (Donnan, 1996). These functions indicate the relationship between abatement costs and increasingly more stringent emission reduction (or risk reduction) requirements. In other words, they map the increase in the per unit costs of emissions abatement/risk reduction associated with the adoption of tighter levels of control. Only costs are (usually) considered in the development of these functions, where this usually includes both the non-recurring (i.e. capital) and recurring (annual operating and maintenance) costs associated with an emissions abatement/risk reduction measure. The result of this form of analysis is often an indication of the cost-effectiveness of a particular measure, expressed in terms of the money unit per physical unit of emission/risk reduction.

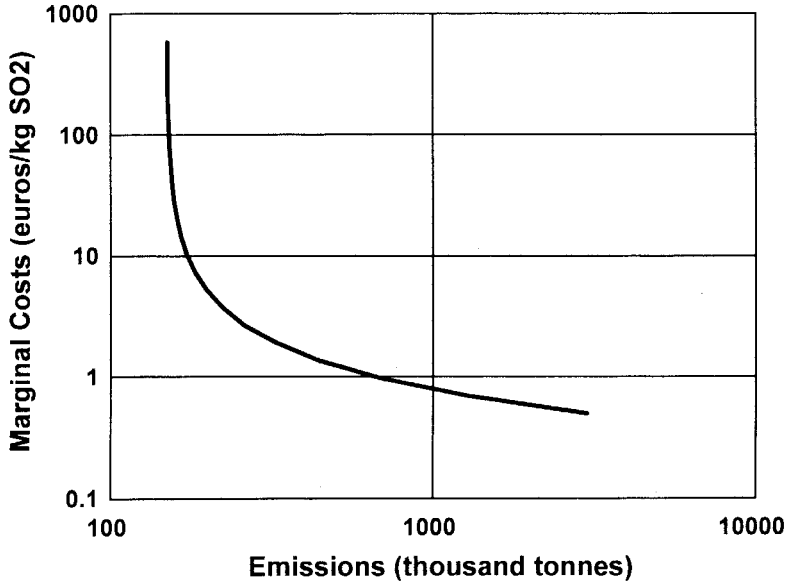
This type of analysis would not usually be used on its own as providing the basis for an SEA. Instead, it acts as a key data source for the preparation of financial analyses, CBAs and CEAs.

Box 4(b): Estimation of Abatement Cost Functions for SO_2 Control in the EU

The first step in developing an SO abatement cost function is to calculate the costs of emissions reductions associated with different levels of reduction: for example, 40%, 50%, 70%, 80%, 90%, 95% reduction levels. In many cases, estimating these costs will require consideration of a number of different control technologies, with lower cost technologies being able to deliver the lower levels of reduction and more costly technologies being required to achieve the higher levels of reduction. As a result, the additional, or marginal, costs of achieving each extra unit of emission reduction can be expected to rise.

Discounted cash flow techniques are used to reduce the stream of non-recurring and recurring costs to a single present value in a given base year. To allow comparison between measures with different operating lives, and to generate estimates that are comparable with estimates of the annual benefits of reduced atmospheric emissions, the present value of the total cost stream of each measure is annualised over the expected period of a plant's operating life. This results in calculation of the equivalent annual cost for a particular abatement technology.

This equivalent annual cost estimate is then normalised by the level of emission reduction achieved to calculate the marginal costs of abatement (in ECU) per kilogram/tonne of pollutant abated. The figure provided below illustrates the marginal cost curve for the control of SO in the UK, based on the adoption of a range of different abatement techniques.



Source: IVM *et al.* (1997)

One area of chemical risk management in which such functions have been used extensively is that of air quality regulation. Box 4(b) illustrates how such functions are derived to allow comparisons across emission reduction measures. It indicates the form of these functions based on a study carried out for the EC involving an economic evaluation of air quality targets (IVM *et al.*, 1997).

4.4 Financial Analysis and Option Cost Assessment

Financial analysis is aimed at determining the impact a proposed regulation will have on industry and the associated impacts on overall competitiveness. It differs from CBA, in that it focuses on estimating the financial costs and benefits (in terms of a decreased or increased cash flow) to different industrial/business sectors and how these affect the financial performance of companies, government or individuals impacted by policies and programmes, while CBA covers a wider range of costs and benefits and measures these in opportunity cost terms (see Section 4.5).

The objective of these analyses is to indicate whether or not industry, and individual companies within an affected market sector(s), can afford to implement a proposed regulatory measure. Given its focus, this type of analysis often requires that special attention is paid to the impacts upon small and medium-sized enterprises (SMEs), as they may not be as able as larger companies to absorb cost increases.

A range of different financial indicators may be used in such analyses, where these include impacts on:

- before and after tax profits;
- capital investment;
- global market share and competitiveness;
- levels of imports and exports;
- distributive effects within an industry sector; and
- in some cases, the impacts of increased product prices on consumers.

Across the OECD, financial analysis is known by a range of different titles. For example, such analyses may go under the heading of ‘Compliance Cost Assessments’ or ‘Business Impact Test’. The aims of those countries which require such analyses as part of chemical regulation (and regulation more generally) are illustrated by those given in the UK guidelines on compliance cost assessment, which state that such analyses are intended to (DTi, 1996):

- show the likely cost implications for business of complying with new or amended regulations; and

- aid regulators in ensuring that new or amended regulations do not impose unnecessary burdens on business.

As will be seen from the discussion that follows, much of the information developed as part of a financial analysis is also required for CBAs and CEAs. For example, in the UK what is required within a compliance cost assessment has expanded such that these analyses have moved closer to being a full regulatory analysis (although the costs considered only tend to impact upon industry). As a result, many of the same analytical issues arise concerning setting the analysis baseline, specifying the relevant time horizon for the analysis, discounting to convert future values to present values, and undertaking sensitivity analysis. The two main differences, therefore, are that: a) such analyses are aimed at determining the financial implications for industry, consumers and

the government of a proposed measure; and b) the analysis does not consider these impacts in terms of their economic opportunity costs to the nation as a whole.

4.5 Cost-Benefit Analysis

As indicated above, economic appraisal and, in particular, cost-benefit analysis provides the methodology underlying most of the current guidelines concerning the analysis of regulatory proposals, where this includes chemical risk reduction strategies. Box 4(c) highlights some of the regulatory issues to which CBA has been applied as part of environmental regulation.

Box 4(c): Examples of Environmental Policy Issues Which Have Been Analysed Using CBA

Public health policy	Contaminated land remediation
Product safety	Multi-media standard setting
Worker health and safety	Chemical risk management
Air quality policies	Solid waste management
Water quality policies	Pesticide use and minimisation
Oil pollution control	Agricultural policies
Noise pollution	Nature conservation policies
Natural resource management	Energy planning

The aim of CBA is to determine whether an investment is worthwhile from an economic efficiency perspective, with this driving the requirement to place a monetary value on as many of the impacts of a proposed measure as possible. The underlying assumption is that by valuing all of a measure's effects in economic opportunity cost terms, one can determine the trade-offs that society is willing to make in the allocation of resources among competing demands.[11] As a result, CBA indicates whether or not a particular measure is 'justified', in that the benefits to society outweigh the costs to society, and allows comparison of alternative options on this basis.

As the analysis of potential risk management measures is only concerned with the additional or incremental costs and benefits arising from a proposed alternative, the aim in CBA is to calculate the monetary value of the changes that would occur under a particular regulatory option compared with the current situation (or base case) or a less stringent alternative. These may include:

- costs (or savings) stemming from changes in production, use and consumption of the

11 The preferred measure of economic impact is the opportunity cost of the resources used or the benefits forgone as a result of the regulatory action. Opportunity costs include, but are not limited to, private sector compliance costs and government administrative costs. Opportunity costs also include losses in 'consumer' or 'producer' surpluses, discomfort or inconvenience, and loss of time. Producer surplus is a measure of the benefit to the producers resulting from the difference between the price currently being paid for a product and the minimum price at which they are willing to sell the product or service to maintain the same level of supply. Consumer surplus is the difference between the price consumers are currently paying for a good or service and the maximum amount they are willing to pay. The opportunity cost of an alternative also incorporates the value of the benefits foregone as a consequence of that alternative. For example, the societal opportunity cost of banning a hazardous chemical is the foregone benefit of that product, taking into account the mitigating effects of potential substitutes.

hazardous substance under examination; for example, in the case of metals this may include those costs arising from mining, smelting, formulation of a metal-containing substance, use of the substance, and purchase of the end product;

- human health effects, where these include acute and chronic effects, from non-severe illnesses to increased levels of mortality, and impacts on different segments of the population (workers, the general public, specific sensitive groups); and

- environmental effects, where these include direct effects on ecological systems and on society's direct use of the environment (whether now or in the future) and those effects which are of a concern from conservation and preservation perspectives.

The assessment of these different types of costs and benefits are discussed further in Sections 5 and 6. It is important to recognise, however, that it is unlikely that all of the costs and benefits arising from a risk reduction measure can be quantified and valued in monetary terms, owing mainly to lack of the necessary data. This is particularly true with regard to impacts on human health and the environment. Although valuation techniques have been developed to help derive monetary valuations of such impacts, as discussed in Box 4(d), the data or resource required to apply these techniques may not be available for any given analysis. This inability to quantify and/or value particular costs or benefits is not necessarily restricted to human health and environmental effects, however. It may also affect the assessment of impacts on the private sector, consumers, regulators, and the economy more generally.

With regard to chemical risk management, a CBA that involves only the partial monetary valuation of impacts is sometimes termed a 'risk-benefit analysis'. In this case, 'risk' relates to the environmental or human health damage arising from a chemical's use, while 'benefit' relates to the reduced costs associated with continued use of the chemical of concern. This is the phrase adopted, for example, in the EC *Technical Guidance on Development of Risk Reduction Strategies* (EC, 1998) and results in part from the nature of the outputs of the preceding risk assessment, which are in the form of the ratio of predicted environmental concentrations to predicted no effect concentrations (see also Section 6). Where full probabilistic risk assessments are undertaken, full quantification and monetary valuation are more likely to take place, as is generally the case in Canada and the US.

Box 4(d): The Economics Valuation Techniques

A range of valuation techniques are used to derive monetary valuations for human health and environmental effects, with value being defined by individuals' preferences. These preferences are obtained by measuring either individuals' (and hence society's) *willingness to pay* for a benefit (or to avoid a cost) or their *willingness to accept* compensation for a loss. The techniques used to derive these measures involve analysis of the market value of gains and losses, *revealed* preferences or *stated* preferences.

Market Effects

For some types of effects, willingness to pay can be derived directly by estimating the value of gains or losses resulting from an environmental change by linking market and production data to dose-response functions. An example is the linking of changes in air quality to changes in crop yields and hence crop value.

Revealed Preferences

These preferences are those that are actually revealed through actual choices made by individuals in the marketplace. In this case, a value is inferred from expenditure on goods or services which embody the health or environmental characteristic of concern; such goods may be substitutes for, or complements to, the health or environmental attribute (e.g. organic food and pesticides, or property prices and clean air). The techniques included under this heading are:

- random utility/discrete choice models;
- averting behaviour;
- hedonic pricing; and
- travel cost method.

Stated Preferences

These are the preferences stated by individuals when asked to value an environmental or health good within a hypothetical market setting. In these cases, the questionnaires are used to construct the hypothetical market and provide the basis for eliciting individuals' willingness to pay. The two key techniques are:

- contingent valuation; and
- contingent ranking/conjoint analysis.

Source: After EFTEC (1998); for further discussion on these methods, see also Freeman (1993) and OECD (1995b)

Box 4(e) summarises the decision criteria used in both partial and full monetary CBAs to identify the preferred option. However, given that it is unlikely that all impacts can be valued in monetary terms for direct inclusion in the CBA, it will be important that any non-monetised impacts are balanced against the estimated costs and benefits in the final assessment. In order to ensure that such a balance is achieved, the final analysis should highlight the full trade-offs involved in selecting different risk reduction options. In particular, care should be taken to ensure that non-quantified effects are not automatically given less weight and thus overshadowed by those which

have been quantified and valued. Similarly, care should be taken to ensure that non-quantifiable effects are not automatically assumed to be of greater value than any of the quantified costs and benefits.

Box 4(e): Decision Criteria in CBA

The standard procedure used in the aggregation of monetised costs and benefits is to calculate net present values (NPVs) and benefit-cost ratios (BCRs):

NPV is found by summing the stream of discounted costs and benefits over the time horizon of the analysis; while

BCR is found by dividing the discounted stream of benefits by the discounted stream of costs.

In the context of risk management, it will be preferable if the 'costs' are represented by the losses to industry and consumers (producer and consumer surplus) and any environmental or human health damages resulting from risk reduction, while the 'benefits' are the environmental and human health gains together with any gains to industry or consumers stemming from control. A positive NPV would then indicate that the environmental and health benefits outweigh any private and social costs, and that the risk reduction measure is justified. If the NPV is negative, the risk reduction measure would not be justified in economic terms.

If one had an unlimited risk reduction budget, it would be desirable to undertake all the non-mutually exclusive measures for which the NPV is greater than zero. When the budget is limited, so as to permit only a subset of justifiable measures to be undertaken, investment funds take on a premium. In such cases, it becomes important also to calculate the BCR, which, because it is a ratio, indicates the option or measure which provides the greatest level of benefit per unit of expenditure.

Two methods which can be used to directly relate economic estimates to non-monetised elements are:

- calculation of implicit values: this involves asking how large the non-valued impacts (e.g. health and environmental effects) would have to be in order for these to be equal to, or greater than, the economic estimates of impact (e.g. the costs to industry and consumers); and

- calculation of switching values: when assessing the importance of different impacts or comparing different control options, it may be important to calculate the implicit values which would have to be placed on the different non-valued impacts in order to 'switch' the ranking of options; for example, this approach could be used to determine how great the value placed on a unit of environmental damages would have to be to outweigh reductions in human health impacts where the adoption of a substitute chemical would result in a shift of risks from human receptors to environmental receptors.

Because of the potential costs associated with undertaking a CBA, criteria have been proposed in the past for determining when a full CBA may be required.[12] However, an approach which is preferred by most regulators is one which allows greater flexibility, with the sophistication of the analysis varying in proportion to the potential implications of a regulatory measure. This may be determined not just by considering the benefits provided by the continued use of a chemical (in terms of lives saved, less expensive and/or better quality crops, lower product costs, etc.) but also by the potential importance of human health and environment benefits.

4.6 Cost-Effectiveness Analysis

4.6.1 General Approach

The most common alternative to undertaking a CBA is to undertake a cost-effectiveness analysis (CEA). The aim of CEA is to develop a ratio which indicates the per unit costs of achieving a per unit reduction in a specified physical outcome. The numerator or 'cost' element represents the estimated resource costs of meeting the target or of adopting a particular measure, while the denominator reflects the relevant physical outcome. Examples of such ratios are given by calculations of the cost per statistical life saved or the cost per unit of contaminant reduced associated with a risk reduction measure.

Two different approaches can be adopted when using CEA:

- the first involves determining which option out of a set of competing measures provides the least-cost approach to achieving a desired and pre-specified outcome; while
- the second involves calculation of the implicit economic value which would have to be placed on results for a decision to be justified and comparison of this to other decisions or a maximum value.

4.6.2 Determining the Least-Cost Option

With regard to the first approach, the CEA may vary from being a simple comparison of one or two alternative measures to a sophisticated analysis of alternative strategies involving different packages of risk reduction measures (drawing on linear programming and other mathematical optimisation techniques). In either case, targets or goals (e.g. acceptable risk criteria or environmental critical load values) are set, with the CEA then aimed at finding the least-cost abatement strategy. Targets may be related to the minimisation of risks associated with the production of a particular chemical, its use as an additive or processing agent, or the use of an end product containing the chemical. Alternatively, targets may be specified at a higher level, for example the reduction of respiratory illnesses and deaths arising from atmospheric emissions (where the focus may be on a single pollutant or a group of pollutants). In more sophisticated analyses, a range of targets or constraints may be set in relation to time, costs, pollutant concentrations, etc.

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12 For example, it has been proposed in the US that full analyses are undertaken for those regulations likely to result in cost impacts on the economy of $100 million or more, would result in major increases in costs or prices to consumers, industry or government, or would have significant effects on competition, employment, etc.

Where risk reduction targets can be specified, CEA is focused on determining the costs associated with the different technologies or strategies for meeting them. These results, when applied across a range of competing measures, can be used to rank the different options in terms of relative cost per unit of benefit. This is a frequent application as part of regulatory decision making. For example, CEA is used in this manner by the US EPA as part of the pesticide programme (Reinert *et al.*, 1990). Costs are typically measured as foregone economic benefits of pesticide use plus any costs of complying with regulations, while effectiveness is defined as the level of risk reduction achieved through introduction of a control. The cost-effectiveness of the control is then measured by dividing the annual net benefit by the annual net risk reduction. The result is a unit figure, such as ECU 4 million per cancer case avoided, which is then often compared to some baseline value to determine whether or not control is justified.

The setting of strict targets in this manner negates the need for the analysis to also estimate the social benefits stemming from risk reduction (even though the benefits may vary between options and the differences in such variations may be important). Underlying the target-setting process is the assumption that the social benefits of meeting that target will outweigh the social costs. This assumption gives rise to one of the key criticisms concerning the use of CEA for regulatory options appraisal. This is that it does not automatically address the question of whether the benefits of regulation outweigh the costs (as does CBA). In other words, it does not consider how much society is willing or able to pay to obtain improvements in health or the environment. A second criticism is that CEA on its own provides no means of addressing equity and distributional issues which may be central to public concerns (although this criticism applies equally to other techniques).

Other criticisms have arisen in the healthcare field over the failure of CEAs to adopt a common or standardised approach which would allow for the results of different studies to be compared. In particular, a panel on cost-effectiveness analysis stressed the importance of adopting a societal perspective when undertaking such analyses to ensure that resource costs are taken into account (Russell *et al.*, 1996).

4.6.3 Comparative Assessment of Measures

Where risk reduction criteria are not pre-specified, CEA can be used to derive the implicit value which would have to be placed on a level of risk reduction for an action to be justified. CEA is used extensively in the field of health care for evaluating the outcomes and costs associated with different medical interventions. For example, CEA is used in such cases to determine the cost per life year gained. A variation of CEA based on assessment of the cost per quality adjusted life year (QALY) is also commonly used by health services. Further discussion of QALYs is provided in Box 4(f).

This type of approach is also applied in chemical risk management, with an example application of CEA in this manner given in Box 4(g). Although this example relates to a past decision, the approach to determining the cost-effectiveness of a proposed risk reduction measure would be similar. Of particular note is the researcher's conclusion that the original policy was not cost-effective, highlighting the importance of undertaking such analyses on all policies in the future to avoid further misallocations of resources.

Box 4(f): Quality Adjusted Life Years and CEA

CEA based on the use of QALYs differs from the more standard approach of estimating the cost per statistical life saved, in that the concept of 'saving' a life is not valid across most medical interventions as they have very little effect on overall mortality rates. Instead, QALYs are based on the concept of maintaining life for an added number of years, or enhancing the quality of life for a given length of time.

Within the QALY approach, the number of life years expected to result from a specified medical intervention (adjusted for any residual suffering, lack of mobility, etc.) are estimated, together with the costs of the intervention. This enables comparisons to be made between different interventions and between those which offer a complete cure and those which only partially alleviate ill health. However, a cost-per-QALY analysis alone does not give a means of determining whether or not a medical intervention will provide value for money, and there are a number of reasons why costs should vary between interventions relating to uncertainty, risk aversion, distribution of risk and levels associated with suffering.

Given that QALYs measure the number of life years gained (with weights attached to reflect quality of life) for a particular policy measure, and their usual measure is 'policy *x* results in 10,000 QALYs gained', their incorporation into economic analyses is problematic. For example, the first step for inclusion within a CBA framework is to convert the QALY into monetary values. A simple annualisation approach may not be sufficient to capture society's willingness to pay and hence its preferences. Some people may be willing to pay more than others to extend their lives.

Box 4(g): Prevention of Minamata Disease in Japan

Following outbreaks of Minamata Disease in Japan in the 1960s and 1970s, the Japanese government introduced a series of measures aimed at reducing its incidence, which was thought to be caused by organic mercury. A ban on the use of mercury electrode processes in the production of caustic soda was thus implemented in 1973.

A retrospective analysis of the ban evaluated the level of risk reduction achieved, the benefits to human health and the costs of implementation. The study found that after taking into account the volume of mercury electrode being used and average life expectancies, the decision translated to an implicit value of 570 million yen per statistical life year extended under conservative (lower bound) assumptions, and of 5,700 million yen per statistical life year extended under the more likely scenario. As a comparison, similar chemical risk reduction policies aimed at reducing cancer effects suggest figures of 24 million yen and lower per life year saved.

The study argues that the original policy was far from cost-effective. It maintains that, although the replacement process is excellent in reducing mercury emissions and in energy conservation, the costs of risk reduction could have been significantly lower if the new technology had been introduced as industry renewed existing plants. The study concludes that such analyses should be undertaken on all policies in the future to avoid such misallocations of resources occurring in the future.

Source: Nakanishi (1998)

Similar conclusions have been drawn from other studies which have applied CEA in a retrospective manner to compare the cost-effectiveness of alternative policies in delivering similar results. This work has focused on examining the costs per statistical life saved (or costs per statistical life year saved) associated with a range of different interventions, including health care, domestic/life style, transportation, occupational health and safety, and environmental interventions. The most notable studies have been undertaken in the US, with work carried out by Tengs *et al.* (1995) involving the comparison of some 500 'life-saving interventions' in terms of the cost per

life year saved. This study found median values for different types of intervention as follows (in 1993 US dollars):

- medical intervention costs: $19,000/life year;
- injury reduction: $48,000/life year; and
- toxin control: $2,800,000/life year.

The research highlights the considerable difference in the median value for toxin control as compared to either medical interventions or injury reduction. This disparity in the median cost per life year saved between environmental measures and other forms of intervention is also found in research undertaken in Japan (Kishimoto, 1997) and Sweden (Ramsberg and Sjöberg, 1997). Although there are valid reasons for such a disparity arising, with the key one being that most environmental policies have objectives other than saving lives, it still raises concerns over the potential inconsistencies arising in the current patterns of social investments.

The findings of this type of research have led to calls for much greater use of CEA as part of health and safety policy making, where this includes chemical risk regulation. In particular, it has been suggested that 'rules of thumb' based on cost-effectiveness indicators are established to guide environmental policy making. One suggestion is that a threshold value is set, for example $5 million per life saved, and that all interventions costing less than this value go ahead and that all costing more are not implemented.

However, care is also required when applying CEA in this manner. As pointed out by several authors (Tengs *et al.*, 1995; Ramsberg and Sjöberg, 1997), such calculations can suffer from a number of problems, for example:

- when the cost estimates do not reflect the full social costs of the intervention, as would be measured by opportunity costs;

- where the proposed measure would not achieve a continuous level of effectiveness per unit of expenditure (e.g. a limited number of individuals can benefit from the proposed measure); and

- when the proposed measure has objectives other than saving lives, where these may include reducing morbidity effects or reducing environmental impacts.

The latter factor, in particular, has often been highlighted as an issue with regard to the use of implicit value CEA calculations. Where a number of adverse effects may occur (e.g. human health and environmental), however, the implicit value will relate to all the various effects and it is unlikely that apportionment between effects will be straightforward. This issue is likely to arise in many analyses concerning chemical risk management. A further complication is that different options are likely to lead to varying levels of control, with some options meeting targets and others falling short but involving significantly lower costs. Box 4(h) describes how differing levels of residual risk could be incorporated into CEAs, drawing on a study concerning species conservation. The approach adopted in this latter study may be relevant to chemical risk management, given that similar issues arise over the degree of action required to achieve 'acceptable' levels of risk.

Box 4(h): CEA and Preservation of the Northern Spotted Owl

The northern spotted owl is an endangered species found in old growth forests in the US and Canada. In 1992, a programme aimed at removing the threatened status of the species designated a large area of forest as critical habitat for the owl. This, combined with conservation measures, was predicted to result in the loss of up to 40,000 timber related jobs. To inform the debate as to the most appropriate management plan, researchers derived a marginal cost curve for use in analysing the impact of various management options on the probability of owl survival. The use of such an approach was novel, in that it provided guidance on the appropriate scale of conservation rather than simply examining options which would result in either survival or extinction.

The marginal cost curve was derived from a supply function which related the probability of owl survival to protected habitat capacity, and to welfare losses arising from resultant reductions in timber supply. This curve then revealed the costs associated with increasing the probability of survival by 1% and was used to compare the increase in survival probability associated with moving from one management option to another. Each option was found to fall into that area of the curve where increases in habitat resulted in small increases in the probability of survival (i.e. in the steepest part of the curve). Thus there were found to be only small increases in the chances of survival, while the costs associated with increasing survival probability from 0.91 to 0.95 were estimated at over $8 billion.

Source: Montgomery *et al.* (1994)

4.7 Input-Output and General Equilibrium Models

4.7.1 Introduction

The top-down analytical approaches provided by input-output and general equilibrium models recognise that the implementation of new legislation by individual companies affects their behaviour as 'buyers' and 'sellers'. These changes in behaviour will, in turn, affect other sectors and hence the interactions between sectors, and ultimately the functioning of the entire economy. Such impacts on the interactions between sectors and the associated indirect and secondary effects may be missed in a CBA. As a result, when such effects are expected to be important, for example, where a measure would significantly affect the prices faced by a diverse range of industry sectors, the use of these approaches becomes more important. In such cases, they can be used on their own, or in addition to CBA[13] to prepare a comprehensive SEA.

Although secondary effects may not be important for the majority of chemical risk issues, they will be for some. Only in cases where regulations would have a significant effect on highly integrated sectors of the economy, or on widely used intermediate products, will assessment of the impacts at a macroeconomic level be necessary. (See Kopp *et al.*, 1996, Hahn, 1996, and Gray, 1997, for further discussion.)

[13] The context of conventional CBA is that of partial equilibrium analysis, with the focus being on the direct effects (gains and losses) of a policy in a single or a few related markets.

4.7.2 Input-Output Models

I-O analysis is a method of systematically quantifying the transactions within sectors and the linkages between various sectors in an economy. Each production activity is assumed to act as both a 'supplier' and a 'buyer'. In its capacity as a supplier, an activity sells its output to others within the same sector (e.g. where one chemical acts as an input into the production of a range of other chemicals), to other sectors and to final consumers. As a buyer, it purchases outputs from other producers, as well as labour, capital, raw materials, etc. (the so-called 'primary inputs'). The total value of output from any one activity therefore not only comprises the value of intermediary goods and services purchased from suppliers, but also the value of primary inputs consumed directly in the production process. By 'mapping' the financial flows within and between all productive sectors in the economy, these models have the ability to capture the wider economic effects of an initial direct impact on a particular sector.

The models are flexible and can be used to address a range of economic, fiscal, resource, employment and environmental impacts (as long as the relevant coefficients representing the various relationships are known). Some of the more commonly sought information includes the economic impacts arising from changes in: a particular industry sector's output, employment, wages and salaries, tax regimes, utility rates, etc. Within the context of chemical risk management, they can be used to consider how a change in costs resulting from a change in regulation would affect the economy, or how changes in regulation may affect natural resource use or emission rates by treating these as primary inputs to production (OECD, 1997). When linked to ecosystem or other physical models, for example air dispersion models, it is possible to link emissions to ambient environmental quality, and subsequently to environmental damage.

National and regional economic-environmental I-O models have been created for several countries (Australia, Austria, Canada, Japan, the Netherlands, Norway, the UK and the US), with most of these focused on forecasting levels of atmospheric emissions. In addition to forecasting discharges of emissions or residuals, input-output models can be used to assess both the direct and indirect effect of controlling flows of emissions or residuals from economic activities. The cost of installing new abatement technology, for example, can be added to the primary input costs of an input-output model. Alternatively, the matrix coefficients can be altered to reflect the implementation of abatement technologies. Box 4(i) provides a brief overview of the EMOP model developed to examine the consequences of adopting atmospheric emissions targets in Denmark.

Box 4(i): EMOP and Analysis of Air Emissions Targets in Denmark

To assess the impact of emission restrictions as part of energy policy, an input-output model called EMOP has been developed in Denmark. This model was designed to analyse the interconnections between macroeconomics, energy use and environmental targets (in this case, emissions of CO , SO and NO). As described by Munksgaard and Pedersen (1997) 'EMOP is a static input-output model. The model is an annual flow model, which calculates the consequences for the Danish economy of introducing specific environment targets…the model includes national energy balances, emission coefficients related to physical energy use and a criteria function which is optimised, e.g. by the use of linear programming.'

Using two scenarios: the basic no environmental targets scenario and an 'environmental' scenario (incorporating the Danish government's actual targets), the following has been concluded:

- growth in GNP is possible taking into consideration the environmental restrictions. However, it implies extensive energy substitution and structural changes in sectoral production as well;
- energy substitution is a significant means to meet the three environmental targets. If energy substitution is implemented as in the model, meeting the CO_2 target will incur the highest social costs;
- it is appropriate to use different CO_2 targets for different sectors of industry; and
- only the CO_2 target generates social costs in the form of shadow prices.

The model is still under development and being refined to represent 'reality' as far as possible. This includes making the model more dynamic in capability.

Source: Munksgaard and Pedersen (1997)

The practical use of I-O models as part of chemical risk SEA is limited, as an enormous amount of time and effort is required to collect the basic data and build a suitable model. These models are non-statistical, in that they do not rely on the outputs of econometric or other forms of modelling which use cross-sectional or time series data to develop sectoral relationships. Instead, they require actual industry data, usually collected through detailed surveys, to generate the precise economic relationships and financial flows which exist between sectors at a given point in time, with both the accuracy of the data and level of detail being greater than that required for other modelling techniques. Although this approach simplifies the formulation of a model, it also results in extensive data requirements, with some data likely to be commercially confidential.

Of equal importance, however, are criticisms concerning the assumptions which must be made for the application of environmental quality based models. For example (Hufschmidt, 1990):

- these models generally assume that fixed coefficients can be defined which will accurately describe real production relationships and resultant environmental quality effects. These fixed coefficients may not be valid, particularly when non-marginal changes in output would result from the introduction of a regulation; and

- in addition, the coefficients are based on assumptions that the relationship between production and quality is linear. This may fail to take into account the importance which background concentrations, threshold effects, and exposure rates have in determining

environmental and health effects.

4.7.3 General Equilibrium Models

Applied general equilibrium (GE) models provide a more sophisticated top-down approach for evaluating the effects of a regulatory measure on the economy as a whole. They go beyond I-O models, in that they provide a means of determining the impacts of a policy on the general structure of an economy, levels of economic growth, levels of inter-sectoral activity, factor demand, employment, income and its distribution, trade, investment and environmental quality. Moreover, because they consider both supply and demand interactions, they are capable of dealing with longer planning horizons than are the simple (non-dynamic) input-output models.

GE models essentially simulate markets for production factors, products, etc. with systems of equations specifying supply and demand behaviour across all markets. Because they explicitly model the interactions between markets, they account for the effects that a change in one market makes on all other markets. Thus, they give a relatively accurate estimate of the overall macroeconomic cost of a policy. However, because of the level at which these models operate, they are likely to be inappropriate for most chemical regulations; these models are best used for regulations which are likely to have a major impact on a number of sectors.

Although there are many examples of GE models, the best 'thought-out' models are likely to have the following elements (Zerbe and Dively, 1994):

- a description of the utility functions and budget constraints for households (with households usually being treated as a group of rational economic actors);
- a description of the production functions for different companies within the various sectors of the economy (again, usually treated as a group of rational firms);
- equations specifying interactions between sectors in the economy;
- the government's budget constraint;
- a description of the resource constraints of the economy; and
- assumptions relating to the behaviour of households and companies in the economy.

The data used as the basis for such models, which give the transactions and income flows within an economy, are held in a social accounting matrix (SAM). The SAM will often build upon both I-O models and other national accounts. Where an appropriate I-O model exists, this facilitates the construction of a GE (although care must be taken to ensure that use of the I-O does not result in the adoption of assumptions based on an 'outdated' structure of the economy).

There are several GE models currently in use within the OECD (with OECD, 1997 providing a review of these). Several have been specifically designed to assess the overall economic impact of addressing the enhanced greenhouse effect, with others relating to abatement cost assessments (see Cline, 1992, Boero *et al.,* 1991, Darmstadter and Plantinga, 1991, Edmonds and Barns, 1990, and Hoeller *et al.,* 1990). Box 4(j) describes the 'DICE' model developed by William Nordhaus, which attempts to integrate the economic costs and benefits of greenhouse gas emissions abatement.

Box 4(j): The DICE General Equilibrium Model

The Dynamic Integrated Climate Economy Model (DICE) attempts to integrate the economic costs and benefits of greenhouse gas reductions through a dynamic representation of the scientific links between emissions, concentrations and climate change. DICE constructs a model of optimal economic growth with an additional climate sector and estimates the 'optimal' path for both capital accumulation and greenhouse gas emission reductions. The calculated trajectory can be read as:

- the most efficient path for slowing climate change; or
- the competitive equilibrium among market economies, where the externalities are internalised using the appropriate social shadow prices for greenhouse gases.

The assumptions within the model include:

- time horizon of 400 years;
- initial stocks of capital, labour and technology;
- industries behaving competitively;
- output produced in accordance with a Cobb-Douglas production function;
- population growth and technological change as exogenous;
- capital accumulation determined by optimising the flow of consumption over time;
- a series of emissions, concentrations and climate equations, together with damage functions;
- a greenhouse gas reduction cost function;
- a conventional investment policy variable; and
- a rate of emissions reduction policy variable.

The two key components of the model are the climate damage function and the greenhouse gas reduction cost function (with the latter assuming that an efficient programme could achieve the first 10% reduction at little cost, while a 50% reduction would cost about $200 billion per year). The outputs suggest the most efficient way to curb climate change. The results of alternative approaches are as follows, with the optimal policy assuming that revenues are returned through lump-sum or non-distortionary rebates:

Policy	Control rate %*	Carbon tax ($/tC)	Annualised global impact ($bn)
Optimal policy	8.8	5.24	16.39
20% cut in emissions from 1990 levels	30.8	55.55	-762.50
Tax with wasteful spending	0.3	0.02	-0.56
Tax recycled by lowering other taxes	31.7	59.00	205.97

* reduction of greenhouse gas emissions below baseline as percentage of baseline

It is interesting to note that the policy with the greatest 'benefits' is a carbon tax of $59 per tonne of CO equivalent with revenue recycling (which refers to reductions in taxes on capital, income or consumption). This is in stark contrast to a situation where such revenues are 'wasted', resulting in costs of $0.56 billion.

A number of problems specific to the DICE model have been highlighted (Cline, 1992):

1) The results do not take into account a probabilistic distribution of lower and upper bound warming; if upper bound warming assumptions were adopted, all damages would be 2.25 times higher.
2) The model uses a 50-year thermal lag, and may be underestimating warming.
3) The nature of the abatement costs curve may overestimate costs, as it makes no allowance for technological change.
4) The discount rate assumed is above the 'social' rate, and thus the calculations give too little weight to impacts occurring far into the future.

With regard to chemical risk management, a number of factors constrain the degree to which these models may be of value. GE models start with a representation of what should happen if the economy in question conformed to the assumptions of the model, rather than the more traditional 'bottom up' approaches that take a set of observations relating to what is actually happening (CEC, 1996). In addition, most models start from the assumption that there is no unemployment, with any change in employment levels being the result of voluntary decisions on the part of the workforce. This aspect of GE models causes studies to reach different conclusions regarding the impact on employment of environmental regulation. It has led the OECD (OECD, 1997) to advise that the results of studies using such models should be considered with reservations.

As with input-output models, the inherent complexity of GE models means that the amount of time and effort required to collect the basic data, and build a suitable model, is often prohibitive. In addition, although they can be used to examine impacts over longer time frames, the reliability of any model will decrease as the time frame for the analysis is extended.

4.8 Multi-Criteria Approaches

4.8.1 Overview

Multi-criteria analysis (MCA) has its early basis in economic utility theory and covers a range of techniques for assessing decision problems characterised by a large number of diverse attributes. Ranking and pairwise comparison methods are used within some of these techniques to provide information on individual attributes, with other approaches then used to aggregate information across the different attributes to provide either a single indicator or reduced number of indicators of relative performance.

In contrast to economic appraisal methods, MCA may be much more flexible, as values need not be expressed in monetary terms and different methods can be adopted to allow examination of the importance of different value systems to the end results. A distinction is made within these methods between the impact of an action on a given attribute or criterion and the importance assigned to that criteria. The impact of an action with regard to a given criterion is determined through scoring procedures, while importance is determined by the weight assigned to that criteria. This distinction does not exist within cost-benefit analysis, as the two aspects are measured jointly through the monetary valuation process. In addition, the inclusion of separate and explicit importance weights may be of particular value where there are widely varying viewpoints, as it can allow for consideration of a range of different value systems in assessing the relative costs and benefits and associated trade-offs arising from different risk reduction proposals.

In general, MCA methods involve the following steps:

- the development of a hierarchy or otherwise structuring the problem: this involves breaking the problem into its component parts, for example identifying the set of impact categories which will be used to make the decision;

- the scoring or rating of impacts: for example, performance against each impact criterion is 'scored' on a common (usually linear) scale, such as a proportional scale running from 0 to 100;

- the development and application of a weighting system: weights are derived to reflect the relative importance of different impact criteria; and

- the aggregation of information across the different criteria into an overall measure of impact: for each impact criterion, weighted scores are derived and these are combined to provide a single measure.

An example of the use of a scoring and weighting based approach as part of risk management is given in Box 4(k), which describes the US EPA's Multi-objective Prioritisation System (MOPS). This approach is used to aid in assessing the risks posed by hazardous facilities.

Where MCA is applied as just one part of a wider appraisal, as is likely to be the case in chemical risk management, then it is also likely that the problem will be pre-structured and well defined, with the issues raised by the various stakeholders establishing the criteria or attributes to be considered in the analysis.

The systems used for defining the scores to be assigned to different impacts can then be developed through a number of approaches. Numerical ranges can be developed, based on standard measurement units for different impacts, and scores assigned against these. Alternatively, qualitative descriptors and associated scores can be used in cases where there is no natural unit of measure. The most desirable systems are those based on actual damage functions or on utility functions rather than more simplistic qualitative scales of measurement. To the degree possible, the set of criteria used should be:

- complete, so that it covers all the important aspects of the problem;
- operational, so that it can be meaningfully used within the analysis;
- non-redundant, so that double counting of impacts is avoided; and
- minimal, so that the problem dimension is kept as small as possible.

Box 4(k): The MOPS Scoring and Weighting System

MOPS (a Multi-Objective Prioritisation System) has been designed as a prototype system to assist US EPA staff in adopting a multi-media approach to facility management. This approach differs from traditional practices, in that facilities are managed in terms of their cumulative impacts on air, water and land. The aim is to ensure that the most effective use of the government's resources is achieved in minimising risks to human health and environment. The MOPS provides a risk-based prioritisation system which gives insight into the most effective management strategy for the EPA in its allocation of monitoring, inspection and enforcement resources.

Within the system, the scoring and ranking of a facility is dependent upon four criteria which are applied across the three environmental media (air, water, land):

- violation magnitude (the severity of the facility's violation as determined by the toxicity of the pollutant, the quantity discharged over the permitted level, the number of permitted discharge limits violated, etc.);
- compliance history (behaviour pattern of the facility to differentiate between those facilities consistently out of compliance and first-time violators);
- human health impacts (location of the facility relative to population sectors and recreational areas); and
- ecological impacts (location of endangered species, habitats and wilderness areas).

The user goes through a process involving the scoring of facility performance with respect to the above criteria, indicating the relative importance of the different criteria and developing end rankings across facilities.

It is argued that the system:

- provides a structured ranking approach that utilises a customised but consistent set of criteria;
- provides a basis for determining which evaluation criteria are most appropriate to management of multi-media facilities, their relative importance, and the information required to effectively evaluate discharger impacts; and
- allows the identification of the types of facility impacts which are the most problematic, and thus where additional resources should be targeted or where changes in permitting and enforcement practices are needed.

Source: Keyes and Palmer (1993)

The next steps within the process are weighting and aggregation. The purpose of weighting is to ascribe relative importance to the different areas of concern and/or to weight the relative importance of individual criterion scores falling under different areas of concern. Where no explicit weights are assigned to individual criteria, this implies that each is weighted equally within the aggregated overall index of performance.

The process of defining weighting systems is probably the most controversial step surrounding the use of MCA techniques. The weighting process should be used to represent the relative significance of different concerns. The fundamental problem affecting this process is in determining whose weights are to be used, and in ensuring that the weights are credible and justifiable. How the weights are derived is a crucial step within the application of these techniques, as they will reflect the views and priorities of the person(s) charged with identifying them. A common criticism of MCA is that the weights are defined by decision makers or experts and thus are not representative of the general population. However, this does not have to be the case. Weights can be derived from different stakeholder groups to ensure that any differences in value systems are captured. These varying sets of weights can then be examined individually (through a sensitivity analysis) to determine how adopting different sets affects the analysis results. By

examining the changes in the overall measure of effect associated with the different weighting sets, the key factors affecting the appraisal results can be determined and an understanding gained of the implications of different starting positions.

An alternative approach is to rely on techniques such as Stochastic Multi-attribute Acceptability Analysis (SMAA). This approach does not require the elicitation of weights from stakeholders, but instead identifies the variations in preferences that would make each of the options the most preferred. Through this type of process, SMAA highlights the trade-offs in selecting one measure as opposed to another.

By applying the weighting factors to the individual impact criteria, it is possible to aggregate weighted scores into an overall index or measure of performance (similar to the use of money as a single unit of measure in CBA). However, this collapsing of information is often criticised as eliminating valuable information on the magnitude and hence significance of (potentially extreme) individual effects. Instead, it may be preferable to reduce the level of aggregation and provide a range of performance indicators (e.g. environment, health, economy, consumers).

To date, MCA techniques have not been widely applied as part of chemical risk management. To some extent, this results from the fact that half of the cost versus benefit equation - the cost side - is readily measured in money terms. Because decision makers and others are used to thinking in these terms, the preference of many is to consider the benefits in the same unit of measure. Hence, the greater emphasis placed on CBA as the most appropriate measure.

As discussed in Chapter 6, however, there may be difficulties in deriving money estimates for all environmental and human health effects. In such cases there may be an important role for the greater use of the more sophisticated MCA techniques. Indeed, this is one of the recommendations which has stemmed from research for the Nordic Council of Ministers (Hokkanen and Pellinen, 1997).

5. INDUSTRY AND WIDER MACROECONOMIC EFFECTS

5.1 Introduction

In estimating the costs to industry and consumers which would arise as a result of the adoption of a risk reduction measure, there are essentially five main categories of potential impact which need to be considered. These are:

- changes in the costs faced by industry as a result of the measure, where these may stem from the adoption of substitutes, changes in production processes, increased sampling requirements, changes in packaging, etc.; related changes are those which stem from technical innovation and the development of innovative capabilities;

- changes in the costs faced by regulatory authorities from the need to implement, administer, monitor and enforce the proposed measure;

- changes in the costs faced by consumers, where these include not only changes in end product costs but also changes in product quality and availability; the latter may also include the availability of new products stemming from technical innovations; and

- macroeconomic impacts, where these may include effects on a country's productivity, degree of market freedom, levels of unemployment, distribution of wealth, international competitiveness, etc.

The factors which should be considered when estimating such impacts are discussed below, starting with the impacts on industry.

5.2 Impacts on Industry

5.2.1 The Chain of Trade

Risk reduction measures, depending upon their focus, could impact anywhere on the chain of trade associated with the use of a substance. It is important, therefore, that efforts are made to identify which links in the chain are likely to be affected and the magnitude of those effects. Potential links are:

- raw materials mining, production and transport;
- processing of raw materials to produce secondary products (which may themselves be further processed to provide products for other downstream processes);
- transportation of secondary products;
- production of end consumer goods using secondary products as an input;
- manufacturing, packaging and labelling of consumer products;
- distribution to wholesalers and retailers;
- end use by consumers; and
- post-consumer disposal and treatment.

Given the international nature of many chemical products, the chain of trade may include actors in several countries. As a result, the impacts and their significance may vary considerably over different links and different countries. Box 5(a) illustrates this point by considering those who might be affected by restrictions on the use of phosphate fertilisers containing cadmium impurities.

Box 5(a): Chain of Trade Implications of Restrictions on Cadmium in Fertilisers

Cadmium is a natural component of phosphate rock, the raw material used in the production of phosphate fertilisers. The main sources of phosphate rock are in Africa, the US and the Middle East. There is an increasing trend towards the integration of mining and processing, resulting in production of intermediary products (phosphoric acid) or finished fertiliser products in the countries of origin.

Proposals have been put forward to limit the level of cadmium within phosphate fertilisers to 50 mg Cd/kg P O for use within the European Union. A UK study has concluded that the introduction of these limits would require either selective purchasing of low cadmium phosphate rock ore or the use of a decadmiation treatment process. Both options would increase the costs of fertilisers to farmers within the EU, but might also serve as barriers to trade with a large number of countries. As some of the developing country suppliers rely heavily upon the export revenues generated by the phosphate industry, the loss of trade may have significant impacts on local and national economies. In addition, the higher costs of fertilisers would be passed on through food prices, with consumers facing increased costs for a number of staple foods such as bread and potatoes.

Source: Ives and Foxhall (1996)

In order to understand the implications for different links within the chain of trade, basic information will be required on:

- the different uses of the substance which would be affected, and whether these relate mainly to intermediary products or processes or end products;
- the categories of companies that would be affected by the proposed restriction (e.g. SMEs, larger enterprises, multinational corporations, etc.);
- the number of companies falling into each category, and their distribution among affected countries;
- the levels and value of production and consumption of the target substance across all uses and, more specifically, in the use under examination;
- trends in production and consumption, taking into account past, current and expected legislation; and
- the potential substitutes, their availability, efficacy and associated risks.

5.2.2 Estimating Changes in Costs to Industry and Consumers

Individual companies face a range of options in determining how to produce their outputs or services, including:

- minimising costs (adopting the least-cost option);
- meeting production targets and other short-term objectives;
- maintaining or increasing innovative capability;
- acting consistently with a long-term business strategy;
- acting consistently with long-term commitments to good corporate citizenship, where these may embrace health and environmental policy, community policy, legal and compliance policies, etc.

On the whole, however, the imposition of a regulatory control on the use of a substance will tend to raise the production costs faced by a company, whether due to a direct need to respond to restrictions or through monitoring, reporting and other requirements. In some cases, the company may not be able to pass these increases in costs on to its customers, especially where global competition prevents the company from being able to do this while still retaining its market share. In such cases, companies may experience reduced profits or may be forced to withdraw from a market. In other cases, however, in response to regulatory measures, a company will raise the price of its output to other companies (with such increases occurring directly or indirectly, depending on the nature of the interactions between sectors) and to consumers.

The significance of any changes in the costs of a chemical or product to consumers will depend on the nature of the chemical under investigation. Most chemicals act as 'intermediate products', which are primarily used in the production of other goods. Their costs will usually constitute only a small part of the total costs of the final product. As a result, any impacts on the cost to consumers will be small (equivalent to the increase in costs multiplied by the proportion of those costs as part of total revenue). For example, consider a regulation that led to a 20% increase in the cost of a chemical input, where the cost of that input constituted 5% of end product costs (assuming equal product performance and stable market share): then the resultant price increase to the buyer or consumer of the product would be around only 1%. In such cases, the impacts on the consumer would be small. The main impact the analysis would need to consider is the increase in costs to the producers.

In contrast, where a chemical accounts for a large proportion of end product costs, the impact on consumers may be much more significant. Determining the significance of such impacts for the consumer, however, requires information on the relationship between changes in price and changes in demand (i.e. the elasticity of demand). For many of the chemical products potentially of concern, this type of information is unlikely to be available. But where a regulation impacts upon widely consumed or highly integrated products (such as the costs of energy production), data on such relationships may be available. It is in the latter cases, as discussed in Section 4.7, that it may be important to consider the use of the 'top-down' approaches within an SEA.

Box 5(b) presents a summary of an exercise undertaken several years ago to calculate the costs to industry and consumers associated with a ban on the use of polybrominated flame retardants within the textile industry. It illustrates the relative impact of a ban on industry and consumers.

Box 5(b): Costs to Producers and Consumers of a Ban on PBDE Flame Retardants

Polybrominated diphenyl ethers (PBDEs) act as flame retardants and have been used for this purpose by the textile industry owing to their effectiveness in fire-proofing furnishing fabrics. Research in 1992 concerning the costs of a ban on the use of PBDEs by the UK textile industry indicated that using alternative flame retardants would increase production costs by about £20 million annually, given the alternatives available at the time.

The study also found that significant variations in costs would occur between sectors of the upholstery market, with the synthetic textile segment of the industry bearing the majority of costs. Roughly 6% of the costs would be associated with production of cellulose textiles, while the remaining 94% would be incurred in the production of synthetic textiles. These cost increases also represented about 2% and 10% of the total value of sales for each segment of the industry.

On average, it was estimated that a ban would increase the costs of furniture to end consumers by about 2.5%. There were also concerns over the degree to which the alternatives would provide the same level of flame retardancy, and thus whether the quality of the end product would also be affected.

Source: DoE (1995a)

In determining costs to producers, a chemical must be viewed as part of a package which provides a service to the companies using it. Although it should be possible to trace through the benefits provided by a chemical at each stage (in terms of value added), it may be more appropriate to identify key industries which are as 'near' to the consumer of the end product as possible, and for which the change in chemical costs has a clearly identifiable impact. Not only will this help ensure that double-counting of effects is avoided, but it will also help focus data collection and analysis activities and ensure that they are efficient. Where the chemical is used in more than one application, separate analyses will need to be carried out for reasonable groupings of applications or for each application.

5.2.3 Potential Cost Items

The types of costs which may need to be considered within an analysis can be classified into two types: non-recurring and recurring. Non-recurring costs (mainly capital costs) are the additional one-off costs generated by the new or amended regulation. These costs will include the purchase of any necessary equipment, the costs associated with its installation, and any other costs which will be incurred in order to implement a policy. Examples of typical cost items are:

- plant and machinery;
- buildings and infrastructure;
- legal and other experts fees;
- training, and other associated start-up costs;
- machinery/production down-time;
- computer systems;
- product research and development; and
- surplus or waste management if orderly transition is not allowed.

Recurring costs (or annual costs) are the additional on-going costs generated by a new or amended regulation, with typical cost items including:

- staff costs or time;
- raw material costs and other consumables (energy, utility costs, chemical inputs);
- waste treatment and disposal;
- maintenance activities and replacement parts;
- sampling, testing and monitoring costs
- product development; and
- marketing, licensing and other regulatory compliance activities.

Some of the recurring costs arising from a regulation, resulting from the need to make changes in production processes in order to accommodate a switch to an alternative chemical or as part of more fundamental changes in process technology, may not be obvious at first. One example of a hidden, and potentially unquantifiable cost, is the impact which regulations may have on innovation by reducing the options which are open as part of new product or process development. In contrast, Box 5(c) illustrates how wide-ranging an examination of costs may need to be with the move to alternatives, drawing from an analysis concerning proposals to ban the use of tributyltin anti-fouling paints on ship hulls.

5.2.4 The Need for Industry's Co-operation in Data Collection

Collection of the data required to undertake the cost analysis may not be straightforward. Where a hazardous substance is a minor input to the overall production of a range of end products (within a given category), few data may be available on the level of consumption in relation to a specific use. At a broader level, end product statistics may not be available in the form needed for the analysis. Although these problems are more likely to arise in the case of newer chemicals, they may also affect the analysis of the more well established chemicals.

Furthermore, the data provided by different sources may conflict (for example, on trends and on the potential of different substitutes and their efficacy), and some industry data may be of a commercially confidential or proprietary nature. For example, if figures on production and intermediate use are unpublished, industry may be wary of releasing such information, particularly if the affected market sector is highly competitive. As discussed earlier, it is likely that a range of different sources will have to be tapped, where these include individual companies, trade associations and national/international trade statistics. Co-operation from industry is essential within this process, as most cost data will need to be sourced from them. Trade associations can be particularly important, as they are likely to have an understanding of the issues already, have contacts with relevant experts, and, through their direct links to the affected companies, are likely to be able to generate much of the data required. In some cases, however, aggregation would still be required in order to protect the confidentiality of individual operators.

Box 5(c): Costs to Industry - the Case of Tributyltin Anti-Fouling Paints

One of the key uses of tributyltin (TBT) is as an anti-fouling paint which restricts the growth of seaweeds, barnacles and tubeworms on the hulls of ships. The presence of TBT within the marine environment is particularly deleterious, having severe implications for the viability of shell fisheries. In an assessment of potential risk management options of TBT carried out in 1992, two measures were analysed with regard to vessels over 25 metres in length:

- the imposition of dock management controls for the collection of contaminated waste waters; and
- a total ban on the use of TBT anti-fouling paints.

In analysing the costs associated with the latter measure, a range of different cost items had to be considered:

- the increased costs associated with non-TBT based paint substitutes;
- the additional paint costs associated with the need for more frequent re-applications when using the substitutes;
- increased frequency of dry-docking as a result of the need for more frequent applications, with consequent increases in costs due to a ship being out of service for a greater proportion of time;
- increased fuel costs as a result of less efficient substitutes resulting in increased drag on ship hulls; and
- the potential for shipping to switch to non-EU docks, and thus for a loss of revenues and employment at EU dry-docking facilities.

The study estimated that the costs of a ban (taking into account the first four cost items only) could amount to £1.1 billion over ten years for the EU as a whole. The potential for ships to switch to non-EU docks, where TBT paints could still be applied, raised an additional factor for consideration. In effect, it was suggested that the EU would be bearing the costs of reducing environmental risks even though ships coated with TBT paints could still use EU waters.

Source: RPA (1992)

Although industry is likely to be willing to help (especially if the proposal is to ban a much relied upon chemical), setting unrealistic timescales for completion of a study or making unrealistic time demands may reduce its willingness to co-operate. Both those commissioning assessments and those undertaking them should be aware of the need to avoid this problem.

5.3 Administrative Costs

The introduction of a risk reduction measure may change both the types and magnitude of costs faced by regulatory authorities. Such costs may include:

- administrative costs associated with, for example, licensing an activity;
- inspection and monitoring costs;
- costs of any scientific modelling, sampling and testing;

- enforcement costs; and
- income stemming from changes in taxed activities (although care must be taken in including such losses, as they represent transfer payments from industry to the regulator).

These changes in costs may relate both to the need for investment in new equipment (e.g. monitoring equipment) and to recurring costs (such as worker requirements). The changes may be greatest under those measures which require strict adherence to environmental emission or workplace standards. For example, some measures could introduce new enforcement requirements through the setting of strict emission values, or could reduce such costs through restricting the use of particular chemicals and thus reducing the need for certain types of testing. The cost impacts faced by regulators may be similar to those faced by industry, although measures which are voluntarily adopted by industry may present little change in costs to regulators and only affect some of the administrative costs faced by industry.

5.4 Macroeconomic Effects

Restricting the use of a chemical or product may affect not only the industries directly involved in its production and use, but also the economy more generally. When considering the wider economic effects, the following questions are likely to be relevant:

- What are the likely socio-economic effects of the proposed restriction in terms of employment, loss of production, product development etc., in the short, medium and long term?

- Will the competitiveness of the relevant industries be impacted?

- What other industry and economic sectors (i.e. within the chain of trade) will be affected by the restriction? and

- Which countries are involved in the chain of trade? How will these be affected? Are they all parties to the decision making process?

The nature of the activities to be regulated, and the magnitude of the action required by industry, will dictate whether a regulation will have wider, secondary effects on the economy more generally (as discussed in Section 4).

As discussed above, because most hazardous chemicals act as intermediary goods and will comprise only a small proportion of end product costs, the potential for secondary effects to arise from risk reduction is likely to be minimal; in such cases, they can be ignored. Only in cases where regulations would have a significant effect on highly integrated sectors of the economy, or on widely used primary or intermediary products, will an assessment of the impacts at a macroeconomic level be necessary (for further discussion, see Kopp *et al.*, 1996, Hahn, 1996, and Gray, 1997).

Although some research in the US has found that particular regulations (e.g. the Clean Air and Clean Water Acts) which affect a significant proportion of the economy may impact upon production costs, and output and labour productivity, across all production sectors of any economy (Kopp *et al.,* 1996), studies for the OECD (1997) concluded that:

- the employment effects of environmental policies appear to be small relative to total employment levels, and tend to be swamped by other, more influential changes taking place in the economy; and

- if anything, environmental policies have had a small net beneficial effect on employment, at least in the short- and medium-term.

However, they also noted that these conclusions should not be taken as implying that adverse employment effects do not result from environmental regulatory changes in particular industrial sectors or localities which may be significant. Box 5(d) highlights this point, with reference to the introduction of policies aimed at controlling greenhouse gas emissions and the effect of these on the aluminium smelting industry in Australia.

Box 5(d): Greenhouse Policies and the Australian Aluminium Industry

Aluminium smelting (which is more energy intensive than many industries) may be more severely affected than other Australian industries if electricity prices rise following the adoption of policies to reduce greenhouse gas emissions. Given that Australia relies heavily on coal for electricity generation, the electricity costs to the Australian aluminium industry may rise more than in countries with access to other generating methods (such as gas, hydro and nuclear). The smelting of aluminium in Australia also indirectly involves consumption of large amounts of fossil fuels, and is therefore associated with significant greenhouse gas emissions. The relocation of such smelting activities to countries with lower cost energy may cause many adverse impacts on the local environment, with potentially high structural unemployment and the related social problems.

Source: Neck *et al.* (1992)

Thus, where implementation of a risk management option could result in significant job losses or increased costs to a specific industry in a local or regional economy, this should be made clear by the analysis. It should be noted, however, that the basic assumptions underlying the 'bottom-up' forms of economic analysis (e.g. CBA and CEA) argue that, as a regulation will typically affect the distribution of employment among industries rather than the general level of employment, such effects should be neutral. These arguments are based on assumptions of a free and mobile (flexible) labour market – assumptions which may not hold in some economies or economic conditions. Most guidelines recognise that there may be cases where regulation affects a particularly vulnerable group, and indicate that in such cases the impacts need to be examined more closely.

In so far as labour resources have activity specific skills, however, there may be a net loss in employment which could lead to secondary impacts on the economy. Where inclusion of such effects is likely to be important, owing to the nature of the policy change, application of the 'top-down' modelling approaches will probably be appropriate.

5.5 Innovation and Product Development

It may well be the case that the introduction of a risk reduction measure, be it in terms of a complete phase-out, restricted use of a hazardous substance, or even labelling or handling requirements, will encourage (and increase) product innovation and development. Such

developments may enable industry both to meet risk reduction requirements, and to do so at a lower cost and with more effective or improved products.

Innovation is, of course, a long-term objective of industry. Within this context, therefore, a risk reduction measure may have the effect of bringing forward future developments or provide an increased incentive for investment in innovative research to produce solutions in the short-term. For example, Bucht (1998) states that 'a ban may be an incentive for innovative and profitable development of less hazardous alternatives injecting dynamics into a dead-lock situation.' Two situations where this has occurred are highlighted: in the field of pesticides, and following the Montreal Protocol on the phase-out of production and use of CFCs.

Major international agreements (such as the Montreal Protocol, the Kyoto principles, and regulations that span many countries, e.g. EU Directives) may have the effect of speeding up the innovative cycle, so that new developments occur more quickly than if a measure is introduced gradually at a regional or national level. The globalisation of the world market also means that firms who react the fastest to the potential for new products and markets will have the possibility of increasing market share and profit margins.

Innovation may not only bring benefits to particular firms, but may also benefit a sector as a whole by reducing costs, increasing product performance or reliability, or creating new spin-off products. Consumers may benefit from reduced prices, increased choice, the purchase of more environmentally friendly goods, and so on. The degree of any price change or any change in the range of options available will be product dependent, as it is a function of both the nature of the innovation and the end product. Where consumers are aware that goods have been produced with less damaging substances, there may be additional public relations benefits for the firms involved. Although such benefits may be, on the whole, unquantifiable, they may be seen in terms of strong consumer loyalty, increases in share price and so on.

6. ASSESSMENT OF HEALTH AND ENVIRONMENTAL EFFECTS

6.1 Introduction

In order to ensure that a balance is achieved between the costs of implementing a risk reduction measure and the benefits associated with reduced risks, some assessment of the magnitude and significance of the health and environmental benefits is required. To some extent, the manner in which such changes can be assessed and incorporated within an SEA depends upon the information available from the risk assessment:

- where the output of the risk assessment is expressed as the ratio of the predicted environmental concentration to the predicted no effects concentration [the PEC to PNEC ratio or, for human health effects, predicted exposure to the predicted no observable adverse effect level (NOAEL)], insufficient information will be available to quantify (and thus place monetary values on) any changes in risk; this type of ratio only indicates the potential for harm; or

- where the output involves combining information on the potential for harm with environmental concentration, exposure and population/stock at risk data, quantitative predictions of the frequency of a specified consequence(s) can be developed.

Risk assessments undertaken in the EU for both existing and new substances provide the first type of information, while those carried out in the US and Canada, for example, tend to provide fuller probabilistic consequence analyses. Where the output is in the form of a PEC to PNEC ratio (or exposure to a NOAEL ratio) then any assessment of benefits will either have to be qualitative in nature or rely on the use of some other form of quantification (i.e. drawing upon the use of MCA techniques). Where a fuller probabilistic consequence analysis is provided, there are more options open to the analyst. This type of quantitative information can be used within CEA, CBA (where this may include the potential for monetary valuation) or MCA.

Regardless of the format of the risk information, for all of the potential risks identified by the risk assessment it will be important that the SEA examines:

- the level of uncertainty associated with the risk predictions and the potential implications of this for risk reduction;
- the degree to which each proposed risk reduction measure reduces each of the risks of concern, and any uncertainties associated with the effectiveness of a measure;
- the degree to which risk reduction would give rise to any health or environmental benefits in addition to impacting on the specific risks of concern; and
- the degree to which risk reduction may give rise to new health or environmental risks, for example as a result of industry adopting an alternative process or chemical.

The remainder of this section discusses the types of health and environmental effects which should be considered within the benefit assessment. It also highlights some of the analytical issues which may arise in the assessment process.

6.2 Health Effects

6.2.1 Overview

In assessing human health and safety effects, the analysis should consider both changes in the risk of fatality and changes in the risk of morbidity, where the latter can be further divided into acute effects and the incidence of chronic disease. Table 6.1 sets out the types of risk end points which may need to be considered within a risk assessment for different risk groups under EU risk assessment requirements.[14] It also provides an indication of other related impacts which may need to be examined in the associated SEA.

14 Following the *Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances* and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances.

Table 6.1: Summary of Human Health Risks Considered in EU Risk Assessments		
Risk group	**Risk end points**	**Associated and indirect impacts**
Workers	- Acute toxicity - Irritation - Sensitisation - Repeated dose toxicity - Mutagenicity - Carcinogenicity - Reproductive toxicity	- Fatalities/deaths brought forward - Various morbidity effects - Lost working days and non-working day opportunities - Health care costs - Changes in quality of life - Stress effects related to pain and suffering
General public		
Humans indirectly exposed via the environment	- Consumption of drinking water, crops, milk and meat, fish. - Inhalation of air - Ingestion of soil	
Source: European Commission Regulation 1488/94 and associated documentation		

Within an SEA, it should be recognised that more than one type of health effect may be relevant, as impacts may vary over different population groups. For example, the nature of worker exposure, and thus the risks of concern, may vary significantly from the risks of concern for the general public. Risks to the general public may relate to long-term indirect exposure to a chemical, while worker risks may include these and other more immediate toxic effects. As a result, measures to reduce one type of risk (e.g. to reduce direct worker exposure to immediate risks) may not address all of the risks of concern. The benefits provided by alternative risk reduction measures may, therefore, vary significantly where more than one population is at risk and where the activities giving rise to the risks vary.

6.2.2 Assessment of Fatality-Related Effects

As noted above, assessment of fatality-related health risks, and hence the benefits of risk reduction, can be carried out in a number of ways. At the simplest level, the assessment may only be able to indicate that the risk of fatalities occurring are reduced to an acceptable level on the basis of acceptable dose information. At a more detailed level, the assessment may be able to determine the change in the likely number of fatalities occurring per year for a particular population group or the public more generally. The first type of information limits the discussion of benefits to one which is qualitative in nature, while the second allows the use of semi-quantitative techniques, such as CEA.

Where the data exist and are considered acceptable, it may be possible to attach a monetary value to changes in the expected number of fatalities drawing on the techniques used within CBA. Box 6(a) provides an overview of the general approach to the monetary valuation of fatality effects. As indicated in the box, this is based on deriving estimates of the 'value of a statistical life', which can be achieved through the application of a range of monetary valuation techniques. Although a

detailed discussion of the application of these techniques is beyond the scope of this document.[15] the types of issues which arise in deriving monetary valuations may also be relevant to a qualitative or (non-monetary) quantitative assessment of benefits. These issues include:

- identifying the segments of the population most at risk, where this may relate to the health impaired and/or specific age groups (for example, the elderly have been found to be disproportionately vulnerable to air pollution);

- determining whether the risk of concern relates to a contemporaneous risk of sudden death or latent risks of future deaths from cumulative exposures, as one may be viewed differently from the other; and

- determining whether there are any factors related to the decision context or the characteristics of the risks of concern (e.g. whether it is voluntary, controllable, dreaded, etc.), which may affect the way in which risk reductions are perceived and thus 'valued' by decision makers and the public (for example, see Slovic, 1987, Savage, 1991, McDaniels *et al.*, 1992, and Sunstein, 1997).

In attempting to address these issues within CBAs, analysts have suggested that adjustments are made to existing valuations of a statistical life when transferring these values to other analyses as part of monetary valuation exercises. For example, recent work undertaken for the UK Department of Health on the *Economic Appraisal of the Health Effects of Air Pollution* (DoH, 1999) sets out a series of adjustment factors for deriving a relative value of a statistical life for air pollution, as compared to one specific to road accidents.

15 For further information on the monetary valuation of fatality effects, see, for example, Cropper and Freeman, 1991, for an overview of research, Krupnick *et al.*, 1993, and NERA and CASPAR, 1998.

Box 6(a): Valuation of Changes in Mortality Risks

The valuation of mortality risks is based on determining what individuals would be willing to pay either for a reduction in the risk of a fatality or for extending life by a year. Such valuations are not concerned with determining the value attached to a particular individual's life, but with the value across all of those who might be affected more generally by reducing the risk of premature death, even though the probability of death is still far below one. By concentrating on the total sum that all of those who might be affected would be willing to pay to reduce the risk to them, it is possible to value the benefit of small changes in risk.

The most common approach to deriving such values is to assume that if, for a group of Y individuals (where Y is a large number), each is willing to pay an average of X monetary units to reduce the probability of death of one member of that group, they will altogether be willing to pay XY monetary units to avoid one statistical death. Thus, XY in monetary terms provides an estimate of the 'value of a statistical life' (VOSL). So, for example, if the mean value expressed by respondents to reduce the risk of death by 1 in 1 million is $1, then the value of a statistical life is estimated at $1 million. These calculations therefore reflect the amount of money that it is considered worth spending to achieve a marginal reduction in risk across a whole population.

However, criticisms over the use of VOSLs in the context of hazardous chemicals which are not adjusted for age, health state, and latency of effects have led to the concept of the 'value of statistical life years extended' (VSLY) as an alternative method for expressing reductions in fatality risks. This approach allows distinctions in risk reduction measures to be based on their effects on longevity (Graham, 1995), with VSLY representing the impact of premature death on an average individual's life span (for example, those who die of cancer at the age of 65 may lose 15 or so years of life expectancy). Based on answers to survey questions about routine safety decisions, the value of an average life year can be calculated. Health economists in the US have estimated the value of an average life year, based on willingness to pay measures, at somewhere between $10,000 and $500,000 (Graham, 1995).

In the past, VSLYs have been derived from VOSLs and thus the two approaches should be consistent. However, more effort is currently being placed on the development of VSLYs which are specific to environmental policy questions; the hope is that this work may provide a more robust approach to monetary valuation of mortality related affects in the near future.

A further question is whether a premium should be added for catastrophic or multiple fatality risks. Is the loss of 50 lives from one accident more important than the loss of 50 lives in separate incidents? Many of those who specialise in the risks of major industrial hazards believe that a premium should be associated with the prevention of multiple-fatality events. Research by Slovic *et al.* (1984) and Jones-Lee and Loomes (1994), however, suggests that there is little public support for this view. Instead, the preference of most surveyed is for minimising the number of lives lost overall, rather than for reducing the risk of catastrophic accidents in particular.

6.2.3 Assessment of Morbidity Effects

Similar issues arise with the assessment of morbidity effects, which, as indicated in Table 6.1, can relate to a range of different health end points. These may vary from illnesses which last for only a short period (less than a day) to non-fatal chronic effects. They may or may not result in hospital admissions, and may or may not have significant impacts on an individual's quality of life and range of activity. When assessing the benefits of reduced morbidity risks, it is likely to be important to take such factors into account in addition to any information on the number of reduced cases for any particular end point. Accounting for such differences will be important in considering not only the trade-offs between the benefits of reduced morbidity effects and the costs of alternative risk reduction measures, but also any trade-offs related to the types of effects which may arise (i.e. where risk reduction results in a change in the nature of the risk - for example, from chronic effects to more immediate effects through a change in processes or chemicals used).

As for mortality effects, morbidity effects can be assessed using non-monetary indicators of benefit or through the application of monetary valuation techniques. In this case, monetary valuation of some of the relevant impacts may be more readily achieved (and acceptable) as they relate to actual expenditures (i.e. medical and health care costs) and lost income (lost working days).

However, it should be recognised that many object to the valuation of health effects – mortality and morbidity – with this being seen as inappropriate at best, and unethical or offensive at worst (see Frederick and Fischoff, 1998). Such views have led in the past to a preference for CEA over CBA.

6.3 Environmental Effects

6.3.1 Assessment Issues

In theory, at least, there are few fundamental differences between making risk management decisions for ecological risks and human risks. However, where human health risk management deals with only a single species, ecological risk management is complicated by the great diversity of species, the numerous levels of biological organisation, the huge number of interrelationships between organisms, and the numbers of end points and criteria that might be relevant.

Assessing the full range of environmental risks and then determining their significance or acceptability is far from being a straightforward process. A comprehensive assessment of the benefits of chemical risk reduction would have to consider a wide range of factors including:

- the physical and chemical properties of the chemical;
- the nature of the receiving (physical) environments;
- the behaviour of the chemical in these environments (e.g. binding to particles, breakdown, etc.)
- the concentration of the chemical and any breakdown products in the environment;
- the susceptibility of organisms in the receiving environments;
- the populations of these organisms in the receiving environments;
- how populations of organisms interact as communities and ecosystems;
- the biological effects of the chemical and its breakdown products on these organisms;
- whether synergistic/antagonistic effects with other substances might occur; and

- the predicted risks to these organisms in terms of lethal and sub-lethal effects.

Drawing together these factors into an assessment of environmental benefits would require overlaying information concerning each of the affected communities/ecosystems with information concerning the fate and behaviour of the chemical substance and its breakdown products. This would provide further predictions concerning:

- the change in direct effects on susceptible species, and associated changes in populations through impacts on mortality, dysfunction, reproductive effects, etc.;

- the indirect effects on other species (susceptible or not) through impacts on the directly affected species, and associated alterations to community dynamics; and

- any changes to the physical environment caused by changes in community dynamics.

Unfortunately, listing out the key factors for consideration in a comprehensive environmental risk assessment (and hence benefit assessment) is far easier than incorporating them into an assessment, with the modelling that is required being by no means an exact science. As a result, for all but the most site specific issues, such comprehensive assessments of environmental risks and the benefits of reduced chemical exposure are rarely possible.

Perhaps because of the need to 'rationalise' these complexities, risk management has generally sought to simplify the process somewhat. Risk management in the US, for example, has historically focused on the protection of individual species threatened by isolated risks (Pittinger *et al.*, 1998). However, in the US attention is now turning to consideration of higher levels of biological organisation including populations, communities and ecosystems (although current assessment methods applicable to these higher scales of complexity are seen as lacking where the same level of precision is concerned).

6.3.2 Assessment Approaches

The implications of the above discussion are that the benefit assessment can adopt two different approaches:

- the first is to determine what risks should be reduced by comparing predicted environmental concentrations to predicted no effects concentrations for the most susceptible species within a particular environmental compartment (the EU approach); while

- the second is to predict a range of possible environmental outcomes associated with elevated concentrations for different risk end points of concern.

Table 6.2 summarises the types of environmental risks which are examined in assessments undertaken in the EU. The table also provides examples of further possible end points related to both direct and indirect effects that might be associated with the different types of environmental risk covered by EU assessments but not explicitly addressed by them. It is these latter types of end points which tend to be the focus of the risk assessments, and therefore of the benefit assessments undertaken in North America.

Table 6.2: Summary of Environmental Risks Considered in EU Risk Assessments		
Risk group	**Medium of exposure**	**Associated and indirect impacts not explicitly identified by the risk assessments**
Aquatic organisms	Surface water	- Impacts on natural fisheries and associated ecosystems in terms of species mix, population numbers and support function - Impacts on commercial fisheries through loss of food sources - Impacts on recreational fisheries through loss of certain species, changes in catch rate, size of fish, etc.
Benthic organisms	Sediment	- Impacts on natural ecosystems in terms of species mix, population numbers and support function - Through the above may have impacts on dependent activities (commercial or recreational)
Terrestrial organisms (flora and fauna)	Soil	- Impacts on natural ecosystems in terms of species mix, population numbers and support function - Impacts on agricultural, forestry and other forms of land use - Through the above impacts on amenity or aesthetic quality of land
Fish-eating predators	Fish	- Impacts on natural ecosystems in terms of species mix and populations - Impacts on commercial and recreational fisheries - Impacts on recreation value - e.g. birdwatching (change in number/types of species that can be supported)
Worm-eating predators	Earthworms	- Impacts on natural ecosystems in terms of species mix and populations - Impacts on agricultural, forestry and other forms of land use - Impacts on recreation value of affected land areas - e.g. through change in number/types of species that can be supported
Atmosphere		- Impacts on natural ecosystems in terms of species mix and populations (aquatic ecosystems, forests) - Impact on agriculture (yield and quality) - Impacts on building materials (corrosion and reduced life) - Impacts on recreation - e.g. loss of visibility

Whether an assessment is based on the use of other quantitative or qualitative appraisal methods, the range of potential risks and end points may need to be considered even if they cannot be assessed with equal reliability in terms of the impacts of a proposed risk reduction measure. As for the assessment of health effects, the degree to which the full range of potential effects can be analysed within SEA will depend on:

- the nature of the information provided by the risk assessment;
- the degree to which other data are available on actual concentrations of the chemical in the environment;

- the availability of relevant dose-response relationships; and
- the availability of data on the environmental stock at risk.

Even where a comprehensive risk assessment has been undertaken, assessing the significance of the environmental benefits of risk reduction is a difficult problem. When dealing with risks to human health, levels of damage are generally applicable and these are fairly universal across different geographical areas - for example, a case of severe dermatitis to an individual in London is as significant as a similar case in Paris or Milan.

For the risk manager, this consistency between outcomes makes it relatively easy to consider the trade-offs between risk reduction and costs where human health is concerned. Decisions can be made by comparing, for example, the costs of risk reduction with the predicted decrease in the number of cases per year of a particular outcome; such indicators of cost-effectiveness can be compared to other information concerning previous expenditure to reduce comparable effects or target values (as discussed in Section 4).

In the case of environmental risk management, consistency between either the affected ecosystems or the resulting benefits is rare, making comparisons extremely difficult. This is one of the reasons underlying the use of economic valuation and CBA within regulatory appraisals. Economic valuation stresses the importance of ensuring that the *total economic value* of an environmental asset is considered when assessing the benefits of environmental risk reduction, where this includes values related to the use of the asset – today and in the future – and to the desire to ensure that the asset is being preserved. A range of monetary valuation techniques can be drawn upon to assist with this, including those which use actual data on the market value of losses or gains, those which infer values from consumer behaviour, and those which directly elicit individual's willingness to pay for a specific environmental outcome.[16] The example in Box 6(b) illustrates how the benefits of chemical risk reduction can be taken into account through monetary valuation.

As described in earlier sections, conversion of predicted environmental damage into monetary values provides one means of improving consistency and has the added advantage of converting environmental damage into the same unit as the costs of undertaking risk reduction - i.e. money. However, it may also focus the benefit assessment on those species, communities and ecosystems which have a recognisable value to people, as these are likely to be the easiest to 'convert' into a monetary value. Where risk assessments are not targeted as much towards such end points and/or where these end points have not been translated into a readily understood expression of damage, valuation is much more difficult to undertake.

16 For further discussion of the concept of total economic value and overviews of the different techniques, see, for example, OECD, 1995b, Turner *et al.*, 1994, and Freeman, 1993.

Box 6(b): Valuation of the Impacts of Atrazine on Chesapeake Bay

A study was undertaken for the US EPA to determine the impacts which non-point discharges of the herbicide atrazine had on wildlife and, in particular, commercial and recreational fisheries in Chesapeake Bay. The approach adopted involved the following stages:

1) The load of atrazine to the Bay was estimated, taking into account the half-life of the chemical, the flushing rate of the Bay, rates of application, and the area to which the herbicide was applied.

2) This was followed by construction of the marginal damage function which linked concentrations of atrazine with the presence/absence of submerged aquatic vegetation in the estuary.

3) The reductions in the biomass of submerged aquatic vegetation were then linked to a change in carrying capacity, and thus in catch for fisheries, based on bioeconomic models linking harvest rates to catch, changes in stock of fish and market price.

4) The loss in economic value from impacts on commercial fisheries was then estimated through the generation of supply, demand and marginal cost functions.

5) For recreational fisheries, a relationship was developed which linked the percentage reduction in submerged aquatic vegetation with economic losses.

The results of the analysis indicated that a 40% reduction in aquatic vegetation leads to total losses of about $5 million across both the commercial and recreational fisheries. The study also noted that the approach adopted captured only a subset of the total environmental impacts associated with atrazine.

Source: Kahn (1991)

As a result, concern has been voiced that the attributes of environmental assets traditionally valued by the general public (e.g. hunting, fishing, recreational activities, scenic views, pollution assimilation capacity) do not sufficiently reflect the requirements of well functioning ecosystems. As such, while the public may appreciate the value of an asset as a whole, they may still overlook the ecological significance of a given species or community. This means that there may be a tendency to undervalue, or to not value at all, many of the services provided by ecosystems and, hence, the value of protecting these services. The need to address such concerns, however, has been recognised and preliminary efforts have been made to derive more holistic values for ecosystems (see, for example, Costanza *et al.*, 1997, which provides one such attempt at meeting this challenge).

6.4 Comparing Health and Environmental Benefits

As part of chemical risk management, it is likely that the risk manager will need, at some point in time, to balance increases in one type of risk against decreases in another type. This is particularly true where changes are made in the processes or chemicals used by the risk generating activity. In such cases, a balance may need to be sought between the harm caused by the original chemical to one set of receptors and the likely harm caused as a result of the proposed changes to another,

different set of receptors. Such comparisons may remain within a given risk consideration (e.g. involve a shift from one type of human health effect to another), or may cross the health versus environment boundary and involve a shift from, for example, health concerns to environmental concerns (or vice versa).

One example of the types of trade-offs which may arise is given by the control of the chemicals used in sheep dips, where measures aimed at reducing human health risks may have added to environmental risks. Until recently, organophosphates (OPs) were the group of chemicals most commonly used in sheep dips. Partly because of concerns over their short- and long-term effects on farmers undertaking dipping, synthetic pyrethroid (SP) dips were introduced in the early 1990s. While OPs are still popular with sheep farmers, the popularity of SPs has increased in recent years. However, while SPs are considered much less toxic to those involved in dipping than OPs, they are also some 100 times more toxic to aquatic life than the OPs.

How can such trade-offs be balanced? Ideally, the aim in risk management is to avoid having to make such trade-offs by adopting measures which reduce the risks of concern and do not give rise to any new or additional risks. However, this may not be possible in all cases. To a degree, the decision criteria which can be used in helping determine whether the benefits provided by risk reduction in such cases outweigh the health or environmental damages will depend on the methodology applied. For example, where valuation has been undertaken as part of cost-benefit analysis, the resulting monetary values will indicate the choice which is consistent with individuals' preferences (as measured through their willingness to pay). In all cases, it will be important to provide decision makers with enough information on the trade-offs to ensure that they are properly understood.

Significant considerations may also arise where there is a need to trade off risks to one environmental (or health) compartment against those to another. For example, a possible response to a proposed risk reduction measure may be for industry to increase the level of treatment applied to effluent discharges, so as to reduce concentrations of the chemical of concern reaching the aquatic environment. Although this may reduce risks to aquatic organisms and ecosystems, it may increase risks to the terrestrial environment through the application of sewage sludge to land. Questions then arise as to whether the net environmental risks are lower as a result of the additional effluent treatment or not.

7. KEY ISSUES IN THE APPLICATION OF SEA

7.1 Overview

The aim of SEA is to provide decision makers with useful information regarding the type and extent of the socio-economic impacts arising from actions under consideration, whether these relate to public or private expenditures. This information will help focus discussions on the most appropriate form of risk management, reveal the preferences and value judgements of stakeholders, and avoid the adoption of ineffective measures.

In order to achieve this aim, a number of analytical issues will need to be addressed within the SEA, with many of these holding regardless of the methodology providing the basis for the assessment. Other issues relate to particular forms of analysis, such as CEA and CBA.

The key issues highlighted most often include:

- specification of the 'baseline' for the analysis, where this defines the levels and nature of chemical use in the absence of risk management;
- the reliability of *ex ante* predictions (versus actual *ex post* impacts) of costs and benefits;
- the assessment of substitutes, and assumptions made concerning their availability and cost, strengths and limitations, efficacy and associated risks;
- the incorporation of distributional effects and equity issues in the assessment;
- specification of the time horizon to be adopted for the assessment;
- the management and communication of uncertainty, whether scientific or 'value' related, within the analysis; and
- more specifically to cost analyses, CEA and CBA, the application of discounting to convert future streams of costs and benefits into present day terms.

7.2 Setting the Baseline

The baseline refers to the status of health, environmental and economic conditions in the absence of further risk management; in other words, it describes the present situation and anticipated outcomes with no new actions being taken by government. Determination of what constitutes the baseline is central to conducting any form of SEA, as the costs and benefits of risk management should be assessed in terms of the marginal changes which stem from the introduction of a proposed measure.

The US EPA (EPA, 1997) stresses that co-ordination with risk managers is critical to ensuring that baseline assumptions are consistent with those made within the risk assessment, and that health and environmental end points are addressed in a compatible manner. In defining the assumptions which will form the baseline, the following issues may need to be considered:

- the behaviour of the target industry in the absence of new government action in relation to

the chemical risks in question;

- the impacts of customer demands on the target industry, and thus on product innovation and development; this includes either other industrial sectors acting as customers or the general public;

- the level of current compliance with existing risk management regulations; and

- the potential implications of other new regulations which may have an indirect effect on the chemical risks of concern.

With regard to the above, it is interesting to note that different regulatory agencies assume different starting points when defining the baseline or 'base case' for the analysis. Most appraisals take as the baseline the minimum legal requirements currently affecting industry/employers, on the basis that this is the most appropriate starting assumption for determining the incremental effects of adding to those requirements.

One exception to this approach is the UK Health and Safety Executive (HSE). The HSE used to take as the baseline what employers should have been doing to comply with existing legal duties, yet this has been changed. It now attempts to estimate additional costs and benefits against the background of existing practice, even if this is short of 100% compliance (HSE, 1995). Where non-compliance is a potentially significant issue, sensitivity tests are used to examine the effect of alternative levels of compliance. It is argued that this gives a more realistic indication of the costs which industry/employers will face in meeting new regulatory requirements.

There is a danger, however, that such an approach penalises the introduction of new regulations in areas where existing compliance is poor, not because the regulations are not justified in themselves but because of poor enforcement or other factors. Similarly, there are also cases where the existing practice goes further than what is legally required, and care should be taken that good practice is not penalised.

The potential need to consider more than one set of baseline assumptions is also noted in cases where the baseline is uncertain as one moves into what would happen in the future. For example, guidance issued by the US EPA's Office of Pollution Prevention and Toxics indicates that a range of baseline assumptions concerning future levels of consumption for a chemical may need to be examined, such as (Axelrad, 1993):

- current consumption held constant over time, where changes are likely to be small over time (especially where such changes are difficult to predict);
- levels of consumption which reflect projected year-by-year changes in demand; and
- consumption in a 'representative year', which is then held constant over the time period for the analysis.

7.3 Predicted versus Actual Costs

Related to definition of the analysis baseline are issues concerning the reliability of *ex ante*, or pre-implementation, predictions of the likely costs and benefits. A number of reasons have been hypothesized as to why *ex ante* estimates may differ from actual outcomes (*ex post* effects).

With regard to costs, estimates may be incorrect due to the failure of the analysis to consider all cost elements, an example of this being the failure to consider the installation costs of new

equipment in addition to the capital costs of the equipment itself. Similarly, actual costs may vary as a result of assumptions concerning contingencies within estimates, or when budgets are based on median estimates which are either over-run or are under-cut.

Other reasons for differences in predicted and actual costs include:

- the importance of the timing and dynamics of regulation, and the implementation of the measure by industry. Most companies have short- and long-term financial plans, around which capital investment programmes are formulated. Depending on when a capital investment is made during a company's business cycle, the opportunity cost of capital is likely to vary. This, in turn, will influence the actual cost of any proposed investment;

- the nature of regulatory requirements, for example whether they result in a prescribed process or allow a more flexible approach. It is generally accepted that allowing a company flexibility in how it achieves a risk reduction target is relatively more cost-effective than prescribing exactly how the company should meet the target; non-prescriptive approaches allow companies to find the least-cost way to reduce risks while still meeting their other objectives. For example, under a strict emissions limit based approach, some companies will find it less expensive to change their raw material inputs, others may carry out more recycling, and others may install more on-site treatment equipment/plant;

- technological advances which may affect the cost of existing technologies or of production activities more generally over time. The marginal costs of production for some commodities decline over time, resulting in similar decreases in product prices (as has happened with the costs of chemical production and associated prices). If costs (particularly capital costs) are expected to decline over time, the implementation date of a specific measure will influence actual costs; and

- estimates provided by industry will generally be based on known technology and be reasonably assured of delivery. Any further technology development will result in cheaper, quicker and/or more effective delivery. Industry considers basing estimates on known technology to be appropriate (and honest), and will almost always try to better their projections. Recognition of this phenomenon should enable all stakeholders to explore and better understand the possibilities for either breakthrough technology development success or ongoing minor technology and efficiency improvements ('learning by doing'). In addition, by allowing industry to articulate potential innovations in an open manner, without threats of penalties for failure to deliver these, it may be possible to develop an improved understanding of the likely costs, time requirements and effectiveness of proposed measures.

Even if industry were to provide some indication of the potential for technological change and for cost efficiencies to result from 'learning by doing', the resulting figures may still represent under- or overestimates given the lack of future knowledge (Hahn, 1996). Implementation of a new regulation is likely to lead to resources being directed towards reducing compliance costs. Indeed, once regulation of a particular chemical is proposed, it is likely that producers of the chemical or of potential alternatives will start work either on finding lower cost alternatives, or on other ways of continuing to meet business needs while still meeting risk reduction objectives. As technological change must be viewed as a dynamic force within the economy, with advances occurring over time, it is likely that the compliance costs will be overestimated, particularly costs occurring further into the future.

Just as such improvements in productivity may reduce predicted costs, technological change could affect predictions of the benefits stemming from a proposed regulation. For example, changes in production processes may lead to lower levels of chemical use and thus to reduced environmental risks over time; or changes in chemical formulation may reduce the safety benefits associated with restrictions on the use of a particular substance. The potential implications of technological change on both costs and benefits is likely to be one of the areas leading to the greatest level of uncertainty within an analysis.

In addition, uncertainties surrounding the assessment of health and environmental effects may lead to either under- or overestimates of the benefits associated with particular measures. The following are all reasons why such differences between predicted and actual effects may arise:

- a failure to identify all of the potential health and/or environmental effects associated with a particular chemical; this may stem from an analysis not being comprehensive enough, from a discontinuity between what the SEA analyst requires and the outputs of the risk assessment, or from the cause and effect links not having been made or proven at the time of the assessment;

- uncertainty surrounding dose-response relationships and the environmental stock currently at risk;

- lack of information on the role which one chemical plays as part of a multi-pollutant problem; related to this are failures to account for synergistic or antagonistic effects;

- the perspective adopted within the risk assessment, and whether this is based on worst-case, best-case or median value estimates; and

- a failure to consider the impacts which would arise from the adoption of alternative processes or chemicals.

This latter issue is discussed in more detail below.

7.4 Assessment of Substitutes

7.4.1 Key Considerations

Section 3 highlighted the fact that there are a range of potential options which should be considered when developing chemical risk management strategies, varying from command and control approaches to market instruments, worker safety programmes, product stewardship, engineering controls, product and packaging design, information tools and voluntary agreements. It also emphasised that each of these different options is likely to have different risk, cost and benefit implications. Although the actual requirements associated with each of these types of measures varies, bans on a chemical's use will lead to the need for industry to find ways of replacing it. The alternatives available in such cases may involve changing production techniques or the nature of the end product; alternatively, it may involve the adoption of a replacement chemical.

In either case, it is important that adequate consideration is given to the implications associated with the adoption of alternatives, and in particular to the use of substitute chemicals as direct replacements or as part of the reformulation of a new product aimed at achieving the same end.

The European Commission has identified a number of questions which should be asked when assessing the impacts of a risk reduction measure and the introduction of substitutes (EC, 1997):

- What substances might be used in place of the substance in question? What are their market situations?
- Do these substitutes present a new set of risks? If so, what is the nature of these risks?
- Are the substitutes effective for all of the same situations as the original substance? Will new technology, equipment or processes be required by industry to achieve the required results using the substitutes? What are the associated costs?
- Will there be a loss of production facilities and other specialised capital and technology which was used in the manufacture of the restricted chemicals or products?
- What research and development is necessary in order to switch to the substitutes? Will such activities require significant expenditure? Will retraining of personnel on use of the substitutes be required?
- Will the consumer have the same level of satisfaction with the substitute? and
- Will some products disappear due to a lack of substitutes?

In an ideal world, a full analysis would be undertaken on the range of potential substitutes to determine the risks, costs and benefits associated with their use. Such an analysis would consider not only the change in costs associated with the adoption of a substitute, but also the availability, efficacy and risk potential of possible substitutes.

In practice, however, many regulatory analyses are commissioned after proposals to ban a chemical have been tabled (whether by an international organisation or a national government) or have been promoted by lobby groups. As a result, the analyses have to be undertaken within time constraints. Thus, the detailed examination of substitutes is rarely included within the study remit. Care is therefore required to ensure that implicit assumptions are not being made about the substitutes.

These problems arise in particular when chemicals are considered on an isolated basis. Such problems may be reduced when chemicals which are either of similar structure or are all alternatives for the same use are analysed together. The use of cluster analysis by the US EPA, described in more detail in Box 7(a), provides an example of SEAs which examine risk, cost and benefit trade-offs associated with the regulation of a group of chemicals.

Box 7(a): Use of Cluster Analysis by the US EPA

Cluster analysis involves the examination of a group of closely related chemicals which are used for similar purposes. A good example of its application is in pesticide regulation, particularly as part of special reviews of currently registered products by the US EPA. The basic innovation behind cluster analysis is that, when considering restriction or cancelling of one pesticide, roughly the same results might be reached for other pesticides of a similar chemical formulation and use. Widening the focus may therefore offer economies in conducting the risk analyses and cost-benefit analyses for the set of substances.

Perhaps of more importance, however, is that cluster analysis might lead to different regulatory conclusions than considering each pesticide individually. For example, the results of an analysis of a single pesticide might suggest that the risks of its use outweigh the benefit. This conclusion is based on assumptions concerning the availability and cost of alternative pesticides. Yet if these alternatives are closely related in chemical composition and in environmental effects, they may also be regulated in the near future. As a result, the costs of restricting the first pesticide examined may be underestimated and the near-term benefits overestimated.

Source: UK Pesticides Safety Directorate (1997)

7.4.2 Availability

As indicated above, an important consideration will be the availability of suitable substitute chemicals or products. Some uses of chemicals are being phased out because of the availability of improved production methods or the existence of lower cost, less toxic or better performing substitutes. Where trends are towards the use of alternative processes or products, the impact of a governmental risk reduction measure may be minimal. In other cases, however, little effort will have been put into developing alternatives, owing either to the cost of the associated research and development or to the lack of a current demand for alternatives.

Once there are indications by national governments or other organisations that regulations on the use of certain chemicals, substances or groups of substances are pending, research and development work is likely to follow, fostering some degree of technological change. For some applications, however, the development of substitute chemicals or processes may take a number of years. As a result, restrictions on use could have severe short-term effects on certain industrial sectors and on the provision of certain products.

7.4.3 Efficacy

Consideration of only the replacement product costs associated with a move to a substitute assumes that the move leads to no deterioration in the quality of the final goods produced, and that there exists sufficient flexibility in technology for the firms involved to make alternative arrangements to allow substitution to take place. These may not be valid assumptions in all cases, as substitutes may have a lower efficacy, requiring changes in the processes used and, potentially, the nature of the end product. In such cases, the losses to consumers may be significantly greater than indicated by the replacement product costs alone.

The degree to which substitutes can be considered ‘drop-in’ replacements is often overestimated. This is particularly true in cases where a ban on the use of one chemical could lead to replacement

with a number of different chemical compounds in order to meet the needs of different users. In other cases, the substitutes which are currently available may require extensive reformulation of the original product in order to provide similar levels of performance. There are often no standard measures of efficacy to allow performance comparisons to be made, and there may be only limited information on performance under different operating conditions. Box 7(b) summarises the types of issues which have been identified in studies examining the implications of bans on the use of certain azo-dyes within the EC textile market.

Box 7(b): Efficacy Issues in the Assessment of Substitutes: Proposed Ban on Certain Azo-Dyes

Research has been undertaken for the European Commission into proposals for a ban on the use of certain aromatic amines used in azo-dyes, in applications which would result in direct and prolonged skin contact with dyed cloth. As the nature of the colour of the azo-dyes using these amines is determined by the reaction between two amines, one aromatic amine cannot be simply and easily substituted with another without completely altering the nature and colour of the resulting azo-dye.

Similar colours can be provided by existing dyes in most cases, but for some textiles the most effective dye for achieving a particular colour contains the banned amine. In other cases, the specific colour offered by an azo-dye containing banned amine could only be achieved using a complex mix of alternative dyes. In both cases, the substitute dyes may be less efficacious than the original dyes and may pose their own human health (or environmental) risks.

Source: RPA (1997)

7.4.4 Risk Assessment

When determining the risks associated with potential substitutes, the assessment should in theory follow the same process as that undertaken for the chemical under investigation. However, many substitute chemicals are likely to be new, and there may be only limited data on the risks associated with their use. This has been identified as a problem when undertaking SEAs of pesticide use, for example, where data on the alternatives are generally inadequate to complete full risk assessments (Reinert *et al.*, 1990). In such cases, comparative assessments are undertaken in order to address the issue of risk trade-offs, using qualitative information if necessary.

Even if the information required to prepare a detailed risk assessment covering all of the above issues for each potential substitute were available, carrying out such studies could lead to a never-ending cycle of analysis. This would be inappropriate where decisions are required in the short-term to reduce real risks. Yet it is essential that any decision to ban or restrict the use of one chemical is informed by the full implications of the use of substitute chemicals in terms of their risks to human health and the environment. Risk assessments must therefore furnish information of sufficient quality to provide a reasonable assurance that, in reducing one risk, another risk is not increased.

One simplified approach recommended within the EU is to base the risk assessment on the collection of common and readily available data concerning the risks of each alternative chemical. In the EU, safety data sheets (SDS) for industrial chemicals have a standard format. It may be possible to compare chemicals on the basis of their most dangerous properties, risk phrases which describe each substance's dangerous properties and the associated hazard, and standard safety

phrases which describe the necessary precautions for handling, storing and using the substance. With respect to the environment, categorisation as 'dangerous for the environment' and other associated risk phrases also apply to substances. On the basis of such information, simple comparisons can be made across the alternatives in terms of hazard potential. However, the use of such an approach merits caution and, wherever possible, should be superseded by risk information based on a combination of both hazard and exposure data.

The importance of considering the risks posed by substitutes is highlighted in Box 7(c) by experience in the US with regard to asbestos regulations. On a practical level, the failure to address the risks of substitute chemicals or products may pose a greater threat to the reliability of an analysis than the failure to consider the impact of possible price changes in other related markets. This is because, as discussed earlier, the impact of price changes on intermediary chemicals is likely to be small relative to the total costs of production. Hence any increase in the price of the related market good will have a small impact on total costs.

Box 7(c): Related Markets: the Social Costs of Substitutes and Asbestos Regulations in the US

Related markets, such as those for substitutes, are markets in which either demand or supply is affected by a proposed measure. Changes in these markets can be ignored if 1) product prices do not change and 2) the social costs of the activities in the regulated market and related market are equal. If prices in the related markets change, or if the social costs of the two markets are unequal and quantities change, the analysis should also examine the related market for the substitute chemicals.

In practice, this means that if the substitutes for a banned chemical pose their own risks, whether to health or the environment, the social costs associated with those risks should be examined. The failure to properly examine such risks is one of the reasons cited by a US Appeals Court in overturning the EPA's rule banning certain asbestos products in the late 1980s. In the Court's opinion, the EPA did not adequately consider the risks of substitutes for asbestos. Some of the substitutes consisted of similarly fibrous materials that might pose the same risks to human health as asbestos or even worse.

Source: Arnold (1995)

7.5 Equity and Distributional Effects

Policy makers generally place great importance on equity and distributional issues, wishing to consider the fairness of a proposed measure in terms of the incidence and distribution of benefits and costs as well as net benefits. Such concerns are illustrated by the inclusion of specific requirements for the examination of such issues within SEAs prepared in Canada, the UK and the US. For example, Box 7(d) sets out the criteria to be considered in analyses undertaken for the Ontario Ministry of Environment and Energy, where these relate to assessment of distributional effects on both industry and particular groups within society. Similarly, the UK Health and Safety Executive seeks to identify risks to 'those less able to exercise choice and receiving only diffuse benefits'; it also highlights as a vulnerable group the poorest paid workers, who are the least able to resist deterioration in health and safety standards at work.

Within the US, particular emphasis has been placed on the need to examine 'environmental justice' considerations. In 1994, Executive Order 12898 was issued concerning *Federal Actions to Address*

Environmental Justice in Minority Populations and Low-Income Populations (EPA, 1997). This Executive Order requires federal agencies to adopt strategies to address environmental justice concerns within the context of agency operations, with the definition of environmental justice as used by the US EPA given in Box 7(e) below. In response to this requirement, the US EPA has developed guidance on how such considerations can be incorporated into environmental assessment prepared by the US EPA. In effect, the guidance requires assessment of any disproportionately high and adverse human health or environmental effects on minority or low income populations. This includes consideration of the cumulative effects of a proposed action as well as other environmental stresses which may be affecting a community.

Box 7(d): Distributional and Equity Considerations in SEA

The Ontario Ministry of Environment and Energy recommends that SEAs report on the following distributional and equity considerations, where they include concerns related to impacts on both industry and particular groups within society:

- impacts on income distribution;
- impacts on vulnerable or other particular groups within society;
- variation in effects across firm size, age of plant and existing plant versus new entrants;
- competitiveness and economies of scale within an industry sector, taking into account implications for small versus medium and large companies;
- creation of barriers to entry into a market sector;
- regional employment effects; and
- the effects of proposed regulations on inflation.

Source: Ontario Ministry of Environment and Energy (1996)

Box 7(e): A Definition of Environmental Justice

The US EPA's Office of Environmental Justice offers the following definition:

The fair treatment and meaningful involvement of all people regardless of race, colour, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations and policies. Fair treatment means that no group of people, including racial, ethnic, or socio-economic group should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local and tribal programs and policies.

Source: EPA (1997)

Within the context of risk management, the EPA guidelines stress the importance of ensuring that risk assessments are conducted so as to determine exposure pathways and potential effects on the communities of concern. This information is combined with geographic and demographic data to determine whether distributional issues arise either directly or indirectly through the use of land and water resources at a level above that of the general public. Standard socio-economic models are then used to examine criteria such as employment, income levels, housing, etc. Impacts on other sub-populations, such as workers, the elderly, small businesses, small government entities, regions, etc., are also evaluated if they are especially relevant to a planned action.

Such distributional analyses are conducted routinely. This may involve the partitioning out of information on the costs and benefits by sub-population within an overarching appraisal, or by supplemental analyses conducted for some or all of the options available to the decision maker. One of the other options available for tailoring socio-economic analyses to improve its ability to identify and evaluate environmental justice concerns is through the development of scoring and weighting systems. The aim is to use such systems to combine preliminary information on potential economic impacts with information on other potential impacts. The analysis can then be used to both define decision criteria for additional targeted analyses or studies and to provide supplementary information to decision makers.

The use of MCA based scoring and weighting techniques to allow for the incorporation of equity and distributional effects into wider SEAs is by no means new. For example, there are numerous examples of the use of 'distributional weighting' systems as part of CBAs concerning land use issues and project and policy proposals in developing countries, where equity issues can be of prime importance (EFTEC, 1998). For most developed countries, however, the use of this type of approach is not as common, with such information being provided through supplemental studies. EFTEC (1998) set out three key reasons why 'distributionally weighted' appraisals tend not to be undertaken:

- difficulties arise in obtaining the relevant information on how different groups may be affected and the populations of concern;

- there are serious doubts about whether a policy (such as the restriction of a hazardous substance) should be an instrument of (macroeconomic) policy for correcting income inequalities; and

- adjusting benefits and costs in this way makes the policy inconsistent with the way resources are allocated in other sectors.

A related concern is that of how to take inter-generational equity issues into account, where these relate to impacts expected to exceed 25 to 30 years. The manner in which this concern is managed is related to the use of discounting procedures within SEAs.

7.6 Time Periods

In any analysis, decisions have to be made over the time period to be used in analysing the costs and benefits of a regulation or other action. If the time period adopted for the analysis is considered too short for the life of the policy (e.g. five to ten years), it may fail to take proper account of costs and benefits which will occur further into the future. This is a particular concern with chemical risk management, where, for example, some health and environmental risks may take decades to express themselves. Taking a longer time period will help ensure that future costs and benefits are better accounted for, but will also increase the levels of uncertainty surrounding predictions.

How then is the appropriate time period determined? There are no absolute criteria for establishing what the time period should be for a particular assessment, but a review of current practice indicates that a number of factors may be taken into account:

- the life of relevant capital equipment;
- the timing associated with implementation of different risk management measures;

- the remaining expected life of the chemical under examination; and
- the nature of the environmental or health risks, and whether the benefits of risk reduction would be realised in the short term or longer term.

Perhaps the most commonly used criterion is that of the life of any capital equipment that would be required as a result of risk management. As suggested above, however, setting the time period according to this criterion alone may significantly underestimate either the costs or the benefits. For example, a report by Sustainable Futures (1998) highlights that the time periods relevant to the implementation of different risk management options may differ substantially owing to:

- financial considerations, such as giving industry time to reduce existing stocks of a substance or replacing the capital used in production processes;

- wider economic concerns, where a regulation may result in economic adjustments across a range of sectors resulting from the loss of productive capacity or shifts in activity;

- the unavailability of appropriate substitutes, and thus the need to await results from research and development on alternatives or new production technologies, and the commercialisation of these; and

- the existence of international or interjurisdictional negotiations.

Finally, as the environmental benefits arising from reduced chemical exposure may take 20 years or more to be realised, it is essential that the time period taken for the assessment is adequate to reflect the magnitude of benefits, or that the residual value of the benefits is taken into account. This is a particular concern where such effects are valued in money terms. Linked to this issue are concerns over discounting and the implications of this for environmental and health benefits arising in the longer-term.

7.7 Managing Uncertainty

7.7.1 The Importance of Uncertainty

In an ideal world, an analysis would be conducted with perfect information on risks, costs and benefits, enabling the analyst to state with confidence the socio-economic impacts of the options under consideration. In practice, the data required for an analysis will be characterised by uncertainty[17] or will be missing altogether for certain components.

Uncertainty results from a lack of information or a lack of knowledge about the consequences of a given action. A range of different types of uncertainty may exist, including:

- uncertainty over the future relative prices of key cost components;

- uncertainty over technological change and the way in which affected industries will adapt to a new regulation;

17 Within this context, uncertainty can be defined as the inability to provide precise information owing to a lack of data; in other words, the probability of a given event is not known.

- uncertainties about the wider economic consequences of taking a particular action;

- scientific uncertainties, for example on the mechanisms underlying cause and effect relationships (e.g. threshold effects, synergistic effects, antagonistic effects), the actual levels of individual exposure across populations, the dose-response relationships, and thus the consequences of taking a particular action;

- uncertainties regarding the time frame over which costs and benefits will occur;

- uncertainty as to the most appropriate standard values for use in the analysis, particularly as part of benefit transfer;

- uncertainties associated with modelling activities, particularly with 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.

All of these different types of uncertainty should be taken into account, and it is important that a systematic approach is adopted for managing them within the overall analysis. It is of note that uncertainty also impacts upon the results of risk assessments.

7.7.2 Managing Uncertainty in the Analysis

Sensitivity analysis provides a means of determining the importance of uncertainty to the end results and is a standard requirement of most SEA guidelines. At its simplest level, it is carried out by varying the values assigned to uncertain variables, for example exposure estimates and associated damages to health. In particular, analysts are encouraged to test the sensitivity of the end results to changes in the values of important assumptions or parameters; this may include key cost assumptions, economic valuations (such as the value of a statistical life) and the discount rate in CEAs and CBAs, or the scores or weights assigned to different parameters within an MCA.

The aim of such analyses is to assist risk managers and stakeholders in understanding the level of confidence which can be placed in the assessment results. This is achieved by highlighting any uncertainties which may change the order of preference assigned to the risk management measures under consideration.

Techniques which are commonly used for assessing the importance of uncertainty to an analysis include:

- scenario testing, in which alternative scenarios are defined to represent different cases or outcomes (high versus low, best versus worst) and the results compared to provide information on the importance of different assumptions;

- Monte Carlo analysis and other simulation methods, which involve explicit quantification of the variability in end results associated with different assumptions;

- Delphi methods, which involve the use of experts to derive estimates of the degree of associated uncertainty; and

- meta-analysis which involves combining the data or results of a number of different studies and defining levels of confidence through statistical analysis.

The more sophisticated approaches directly incorporate uncertainty into the analysis by assigning probabilities (which can be either in discrete form or as a distribution) to different outcomes. Through such procedures, the 'expected value' of costs and benefits can be determined (where an expected value can be defined as the sum of individual outcomes times their probability of occurring). An issue in applying this type of approach is that what happens in reality may be very different from the expected value, particularly when the range of uncertainty is large.[18] As a result, further information is generally sought on the range of potential outcomes and the likelihood of 'extreme' results.

In CEA and CBA, sensitivity analysis generally involves considering the effect on NPVs of plausible variations in some of the assumptions made. An alternative approach is to calculate what degree of variation in a particular variable would by itself reduce the NPV to zero, or result in a change in preference between competing options (i.e. the calculation of switching values as discussed in Section 4). The approach is similar in the most commonly used forms of MCA, where sensitivity analysis is likely to involve testing different sets of criteria weights and the impact of these on scheme rankings.

Such analyses can help guide a decision by:

- improving the understanding of an issue by showing more clearly how changes in one variable affect others;

- allowing variations in the design of a risk management measure to be tested, with the aim of either further reducing risks at minimum costs or reducing the costs associated with implementation; and

- identifying key uncertainties affecting the results (i.e. those to which the analysis is sensitive), and thus where any further research would be best targeted.

7.7.3 Value of Information Analysis

Where uncertainty surrounding one more key assumptions is critical to the choice of the risk reduction measure, 'value of information' analysis (VOI) can be used as part of an economic appraisal to determine whether or not it is more appropriate to base a decision on incomplete or inaccurate information, or to delay any actions until sufficient data have been collected to minimise (or at least reduce) the key uncertainties (for a further discussion, see, for example, Thompson and Graham, 1996, and Postle *et al.*, 1984). Value of information analysis therefore allows additional data collection, with a commitment to taking a decision in the future to be considered as an additional, viable option within the decision making process.

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18 From a theoretical perspective, this divergence is not a key problem as long as society is risk neutral and the expected value approach is applied over several regulatory decisions over time. Under these conditions, the performance of the expected value relative to the actual outcomes in any particular decision is not important because the rationale for its use arises from its utility over multiple decisions.

The value of this additional information is derived by considering the expected outcomes with and without the information. The approach therefore relies upon the use of conditional probabilities and expected values. If the additional cost of gaining the extra information is outweighed by its expected benefits (in terms of improving the decision – e.g. decreasing costs or increasing benefits), then it is worthwhile obtaining the additional information.

Of course, there may be good reasons why some gaps in the data and hence uncertainties exist, for example owing to the costs of obtaining the data, time constraints, political reasons, and so on. The political dimension may be particularly important when decision makers are considering delaying a risk reduction measure in order to gain additional information. Pressure from political parties, lobby groups, the media and stakeholders in general may create significant pressure for decision makers (and society) to accept the uncertainties in favour of short-term implementation.

7.8 Discounting

Given the wide range of costs and benefits that will need to be considered within an SEA, there are likely to be significant temporal differences in when they occur. Typically, the costs of risk management will be incurred upon implementation of a measure, while the benefits occur further into the future.

Whether performing a cost analysis, a CEA or a CBA, the stream of costs and/or benefits occurring over time must be reduced to a single figure in order to allow the comparison of risk management measures. This is achieved through the use of discounting procedures in both financial and economic analysis, and applies equally to decisions affecting the private or public sector.

Discounting reflects the assumption that individuals would prefer to have money now rather than some time in the future; future costs and benefits are therefore 'discounted' and attributed a lower weight than those occurring immediately. The higher the discount rate used, the lower the importance placed on future costs and benefits. At any positive discount rate, costs and/or benefits which accrue more than 50 years into the future will have a very small 'present value'.

This raises the following question: What discount rate is appropriate in calculating the present value of a regulation's future costs and benefits? In CBA, the correct discount rate is what is referred to as the *social discount rate*, which reflects the rate at which society as a whole is willing to trade off present for future costs and benefits. When applied to private sector activities and investment in capital, discounting provides a means of taking into account the opportunity costs of investing in one capital use today as opposed to another in the future. The *opportunity cost of capital* is obtained by finding the rate of return on the next best investment of similar risk which is displaced by undertaking a particular project (or, in this case, implementing a risk reduction measure). In regulatory terms, adopting this rate indicates that if a private business can earn a 10% rate of return on its capital investment, it should be able to earn a similar return on its investment in risk management activities (Turner *et al.*, 1994).

Even if investment in capital were not productive, in the sense that it earns returns, people would still prefer to have money now rather than next year. This 'time preference' arises because people are impatient, the future is uncertain (e.g. due to the risks of ill health and death), and people expect to be better off in the future than they are now (reflecting the diminishing marginal utility of consumption – see also Pearce *et al.*, 1989).

Given that the concepts underlying the social rate of time preference are different from those underlying the cost of capital rate, under any realistic assumptions the two rates will not be identical (HM Treasury, 1997), leaving a choice between the use of one rate or the other, or some rate in between.[19] Most governments appear to assume a single number (or a range) lying within a plausible range of both rates (e.g. with rates tending to vary from between 3% and around 6%). Furthermore, although various regulatory agencies have established groups to consider issues such as discounting environmental and health effects, and treatment of inter-generational equity considerations (e.g. the US EPA and the UK), current practice between countries varies only slightly.

It must be noted, however, that in the context of human health and the environment discounting is viewed by some (in particular environmentalists) as being unacceptable (e.g. because all lives have the same value) and in contradiction to sustainable development concepts (as it does not expressly take into account the preferences of future generations, who may value the future more than does the current generation). In response, economists argue that there is no unique relationship between discount rates and environmental degradation. As a result, it is argued that discounting at a positive rate is not inconsistent with sustainability. Furthermore, the failure to discount implies indifference between benefits now and benefits in the future - an assumption which is not consistent with some research findings on this issue (see, for example, Cropper *et al.*, 1994, and Johannesson and Johansson, 1997). In addition, the failure to discount costs but not to discount benefits (whether assessed in money terms or physical units) could lead to the perverse conclusion that it is always better to wait for an investment that saves lives in the future.

In the context of health effects, economists have argued for the use of discount rates which are lower than the standard public sector discount rate,[20] particularly when valuing the prevention of future fatalities (Broome and Ulph, 1991; Jones-Lee and Loomes, 1995). Such arguments led recently to recommendations by a panel of UK experts that a discount rate of 1% should be applied to the discounting of future fatalities in an appraisal of health effects of air pollution (Department of Health, 1999).

In addition, some government agencies have recognised the potential need to adopt lower discount rates when appraisal of a policy depends upon the discounting of effects in the very long term, for example 50 years or more into the future (HM Treasury, 1997).

8. CONCLUSIONS

8.1 The Need for SEA

A range of different options are open to decision makers when faced with questions over how to manage chemical risks. Such options may vary from taking no action to banning the use of the chemical of concern. Choosing either of these options implies that a decision has been made as to whether it provides an acceptable balance between the costs and benefits which would result. But on what basis can such decision be made?

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19 In theory, in equilibrium time preference and cost of capital rates should be the same. In reality, however, they differ owing to distortions, for example from taxation.

20 In essence, it is argued that the pure time preference rate for utility should be used rather than the social time preference rate, which also takes into account the diminishing marginal utility of wealth at higher income levels. See Jones-Lee and Loomes, 1995, for a further discussion.

In order to make such decisions with confidence, information is required on:

- the activities of concern throughout the chemical's life cycle, including production, use and disposal, and the level of risk associated with each of these activities;

- the characteristics of the risk (e.g. persistence of the chemical, nature of the effect, the environmental media and species affected, and human populations affected, such as workers versus general public);

- the implications of any changes in processes or the chemicals used associated with the alternative measures, including information on their effectiveness/efficacy, impacts on product quality, potential to give rise to other risks of concern, and potential for technological development/product innnovation;

- the financial costs of control and their distribution across different stakeholders in the decision, where this may include industry, other businesses, consumers and government agencies;

- the levels of risk reduction in terms of human health and safety and/or environmental benefits which would be achieved by the alternative risk management options; details of the distribution of these benefits geographically and with regard to sensitive populations may also be important; and

- the costs, risks and benefits associated with each of the options, and any key differences (or trade-offs) in the balance between these across the options.

In considering the above, decision makers are being asked to weigh up information on a disparate number of effects, potentially affecting a range of different stakeholders at national and international levels, both in the short and longer term. This will never be a straightforward task.

Against this background, what then is the role of SEA? First and foremost, its aim is to provide decision makers with information of the nature described above in order to assist them in understanding the implications of the actions under consideration. As money spent on reducing one type of chemical risk cannot be spent on other risk reduction activities, the overall objective of SEA is to assist decision makers in making decisions as to the most appropriate allocation of society's resources.

Within this context, SEA also provides a valuable mechanism for involving stakeholders in the decision making process. In this regard, SEA can help in developing a shared understanding of the implications of taking action (or of taking no action), and thus help focus discussions between stakeholders and decision makers as to the advantages and disadvantages of different forms of risk management.

If the SEA is to properly inform the decision making process, it must also provide a systematic assessment of the trade-offs of choosing one option over another. It must therefore bring together the types of information listed above to provide an indication of the implications of adopting one form of risk management over another.

Depending on the characteristics of the risk management problem, the approach taken to developing this information may be qualitative or more quantitative in nature. A qualitative analysis may be sufficient in cases where the risks are obviously high in relation to the costs of

reducing them and there is general agreement on the preferred form of risk management. More quantitative analyses, for example, drawing on the frameworks provided by cost-effectiveness analysis, cost-benefit analysis or multi-criteria analysis, are likely to be required where there are significant resource implications and/or differing opinions on the most appropriate form of risk management.

Although the preparation of comprehensive and systematic analyses has its own resource implications, whether qualitative or quantitative in nature, research has shown that such assessments can improve the quality of chemical risk management decisions. They can assist in ensuring that all factors are taken into account in decision making and that risk management is correctly targeted, in fine-tuning risk reduction measures, in identifying new options, and, through these, in achieving the most cost-effective use of resources.

8.2 Features of a Good SEA

What are the features of a SEA which will fulfil the role set out above? A number of examinations of the application of SEA to environmental regulation have concluded that the quality of SEA could be dramatically improved if those undertaking the analyses 'were to follow a few simple guidelines' (Hahn, 1996). Based on the discussion provided in the preceding sections of this document, a series of key features for SEAs can be identified.

These key features are listed below. The aim in setting out this list of features is not to establish a rigid or prescriptive approach which must be followed, but to highlight the types of considerations which should enter into the more pragmatic selection of tools to be used in any particular case.

1) **Substance or Impact Based Approach**: There is currently a debate as to whether a substance should be assessed at a generic level or as used in a specific process. Overall, assessing the risks posed by chemicals within specific uses will provide more reliable indications not only of the risks associated with those uses, but also of the costs and benefits associated with different forms of control. Similarly, there may be merit in starting with a particular health or environmental problem and working backwards from this to obtain solutions that may include regulation of the chemicals associated with the problem (as distinct from taking the chemical as the starting point). A preliminary screening application of SEA may help inform the process of selecting which health or environmental issues should be given priority.

2) **Estimating and Characterising the Risks**: Usually a risk assessment will have been conducted prior to the SEA. In some cases, this may be a screening level assessment which relies on safety data sheets, previous studies, or other established data sources. In other cases, it may involve comparisons of predicted environmental concentrations to no effects concentrations. Where appropriate, the risk assessment should go beyond the calculation of such risk quotients to the full probabilistic prediction of potential risk outcomes. This will help achieve more fully quantitative SEAs where these are desired for decision making purposes. It is also important that the estimation of risks is transparent, to allow the necessary feedback between the SEA and the identification of alternative risk reduction measures.

3) **Understanding the Chemical Life Cycle**: Once a chemical has been identified as posing a potentially unacceptable risk, it is vital that the manner in which it is used is understood. This will involve an assessment of the different activities within the life cycle of the product, from its production as a raw material to its end use, and determining the

associated chain of trade. Not only will this aid in identifying the industry and business sectors that may be affected, but it should also highlight any potential distributional issues and health or environmental issues which could arise from the use of alternative processes, chemicals or products. This assessment may need to be international in scope and should involve stakeholders.

4) **Identifying Risk Reduction Options**. The above information may also be invaluable in defining an imaginative initial set of risk reduction options spanning the full range of costs and effectiveness. Involving stakeholders in this process will increase the likelihood of achieving the desired risk reduction at costs acceptable to both industry and society. Screening techniques can then be applied to this initial set to define a sub-set of options to be considered in more detail. As indicated above, the definition and subsequent analysis of risk reduction measures should be iterative in nature, with there being linkages to the risk assessment and an on-going process of refinement as necessary.

5) **Identifying the Areas of Impact**: Different risk reduction options are likely to result in different impacts, and care should be taken to ensure that the full range of potential costs and benefits are considered in the analysis. Potential categories of concern include changes in human health and environmental risks, impacts on the costs faced by industry and business (costs of production, competitiveness, etc.), consumers (costs, availability and quality of end products) and regulators (administration, monitoring and enforcement). Where a proposed measure would have significant cost impacts on a wide number of sectors, it may also be important to consider the potential for wider impacts on the economy and employment. The potential role of technological development in reducing costs to industry and business should also be examined.

6) **Involvement of Stakeholders**: Involvement of stakeholders is vital to the SEA process, with such involvement potentially running throughout the process - from identification of options through to the collection of data and making a decision. The stakeholders who should be involved in any particular risk management issue will obviously vary depending on the characteristics of the problem. Potentially, stakeholders include industry, consumer groups, environmental organisations, other interest groups (e.g. representatives of sensitive populations or those representing cultural concerns) and other government agencies. Not only can the involvement of these stakeholders assist in gathering the data required to prepare an SEA, but it should also help in gaining acceptability for the analysis results.

7) **Assessing the Implications of Alternatives**: Some risk reduction measures will rely on the adoption by industry of alternative processes or of alternative chemicals. In some cases, alternatives may be readily available while in others they are not. Where alternatives are readily available, the analysis should consider the implications of adopting the alternatives, including any process, quality or cost penalties associated with their use and the levels of risk they pose to health or the environment. With respect to the latter, care should be taken to ensure that biases are not introduced into the findings because some of the alternatives are new chemicals, for which there is a lack of data on human health and environmental risks or which are unproven in performance terms.

However, it must also be remembered that product or process substitution is the mainstay of pollution prevention. The need to develop alternatives to the current chemicals or production methods being used is a main driver underlying the development of new technologies. It can lead to unanticipated benefits in the form of lower production costs, reduced processing time, reduced costs in meeting regulatory requirements (health and safety or environmental), new product characteristics, new products and hence new

markets, etc. Although the benefits of innovation are hard to predict or quantify, they are critical both to the on-going management of chemical risks and to continued economic growth. Such potential benefits should not be ignored within an assessment.

8) **Assessing the Impact of Alternative Options**: Once those impacted are identified and data have been collected, a systematic assessment should be undertaken to produce information on the costs, risks and benefits associated with the alternative options. This assessment can be either qualitative or quantitative in nature, or involve a combination of both types of information. In general, the greater the level of quantification achieved, the more robust the end results are likely to be. Quantification can also help ensure that important health and environmental issues are given equal consideration to the more traditionally valued impacts on the costs faced by industry, consumers and regulators. The level of sophistication in the analysis, however, should be commensurate with the implications of the decisions to be made. The added time and resource costs associated with quantification, and possibly monetary valuation, of all impacts should be weighed against the added assurance of more informed decision making.

9) **Establishing Standard Assumptions**: The use of standard assumptions concerning key variables such as discount rates can help in ensuring that there is consistency in analyses and hence in regulatory policies. However, agreeing what the standard values should be, particularly for more controversial assumptions, such as the value of an extended life year, may be more difficult where measures are international in scope.

10) **Understanding Equity and Distributional Impacts**: Policy makers are likely to request information on the incidence and distribution of costs and benefits associated within any proposed measure (including inaction). For example, they may seek details on the distribution of costs and benefits across different stakeholder groups (e.g. regulators, industry, other business sectors, consumers, etc.), across different socio-economic and demographic groups (e.g. an ethnic population, the elderly, the poor, etc.), and across different geographic areas (e.g. rural, urban, industrialised, agricultural, etc.).

11) **Establishing the Trade-offs**: The trade-offs associated with the adoption of one risk reduction option over another will need to be clearly presented and described to decision makers to ensure that they have a full understanding of the implications of their decisions. Where quantification (or valuation) has not been feasible, consideration should be given to the use of cost-effectiveness indicators and the calculation of implicit values. Care will be needed to ensure that less weighting is not automatically given to those effects which are not assessed in quantitative terms.

12) **Making Recommendations**: Although it is not the role of the analyst to make decisions, there are a number of recommendations which the analyst may wish to make based on the results of the analysis. These could include recommendations on: the need for peer review of the study results; the value of further data collection to reduce key uncertainties; and the potential need for temporary (or more permanent) exemptions from the proposed measures.

13) **Reporting Procedures**: Presentation of the findings in a clear and transparent manner is central to ensuring that decision makers and stakeholders affected by the decision understand the results and are able to feed them into the decision making process. This includes information on the nature and extent of socio-economic impacts, key assumptions made in the analysis, and the associated key uncertainties. Presenting this information in a readily accessible format can help in building a shared commitment to the effective

implementation of risk reduction measures. Thus, it may be important for procedures to be established concerning reporting on assumptions, uncertainties, and any omissions from the analysis. Not only should this aid with transparency, but it should also help improve consistency across analyses.

Chemical risk management is a complex problem, particularly as action is increasingly being undertaken at an international level. It is therefore vital that the approach adopted for assessing alternative risk management options is one which is open and accessible to all of the relevant stakeholders. Incorporating the features set out above into the analysis should help in improving the quality of risk management decisions and in building the trust required to increase the acceptability of these decisions.

9. REFERENCES AND BIBLIOGRAPHY

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