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ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY
ON CHEMICALS

Series on Risk Management No. 9

**PROCEEDINGS OF THE OECD WORKSHOP ON THE INTEGRATION OF
SOCIO-ECONOMIC ANALYSIS IN CHEMICAL RISK MANAGEMENT
DECISION MAKING**

London, 7 - 9 January 1998

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OECD Environmental Health and Safety Publications

Series on Risk Management

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INTEGRATION OF SOCIO-ECONOMIC ANALYSIS IN
CHEMICAL RISK MANAGEMENT DECISION MAKING**

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IOMC

**INTER-ORGANIZATION PROGRAMME FOR THE
SOUND MANAGEMENT OF CHEMICALS**

**A cooperative agreement among
UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD**

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

**Other Environmental Health and Safety publications related
To risk management include:**

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

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

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

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

Risk Reduction Monograph No. 5: Cadmium. Background and National Experience with Reducing Risk (1994)

OECD Proceedings: Sources of Cadmium in the Environment (1996)

OECD Proceedings: Fertilizers as a Source of Cadmium (1996)

Risk Reduction Monograph No. 6: Methylene Chloride Information Exchange Programme: Survey Results (1996)

Risk Reduction Monograph No. 7: Proceedings of the OECD Workshop on Non-Regulatory Initiatives for Chemical Risk Management (1997)

Risk Reduction Monograph No. 8: Proceedings of the OECD Workshop on the Effective Recycling of Nickel-Cadmium Batteries, Lyon, France, 23-25 September 1997 (1999)

Risk Reduction Monograph No. 10: Proceedings of the OECD Workshop on Sustainable Chemistry, Venice, 15-17 October 1998 (1999)

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About the OECD

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

The work of the OECD related to risk management is carried out by the Working Party on Risk Management, 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 monograph on methylene chloride (see list of publications on page 4). In 1996, OECD Environment Ministers endorsed a **Declaration on Risk Reduction for Lead** to advance national and co-operative efforts to reduce the risks from lead exposure.

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

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

This publication is available electronically, at no charge.

For the complete text of this and many other Environmental Health and Safety publications, consult the OECD's web site (<http://www.oecd.org/ehs/>)

or contact:

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E-mail: ehscont@oecd.org**

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

These Proceedings contain the presentations made at the OECD Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making, held in London on 7-9 January 1998. There is also a report of the Workshop, including participants' conclusions and recommendations. A description is provided of OECD's Risk Management Programme, under which the Workshop was held; the development of methodologies to support Member countries' efforts to manage risks posed by chemical substances; and the role of this Workshop in supporting such activities.

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EXECUTIVE SUMMARY

The OECD Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making took place in London in January 1998. It was organised by the United Kingdom and BIAC (the Business and Industry Advisory Committee to the OECD), in co-operation with Canada, Japan, the United States, the European Commission and TUAC (the Trade Union Advisory Committee to the OECD).

This workshop was designed to bring together analysts and risk managers to further the integration of socio-economic analysis in chemical risk management decision making by:

- providing basic information on the general techniques, approaches and terminology used in the development and application of socio-economic analysis (i.e. describing what exists and how it is used);
- sharing experiences and identifying expertise, identifying effective techniques and approaches, and highlighting any problems encountered and considering solutions. This would include discussions on: when such an analysis might be appropriate (e.g. in a national, regional or international context); where barriers to its wider use exist and how they may be overcome; and what approaches have been used for valuing costs and benefits;
- identifying areas that need further work within the OECD and in Member countries, and the means for carrying such work forward.

Participants attended six sessions which took place in sequence, each adding a layer of information necessary for achieving the workshop's objectives (see the Chairman's Report). These sections comprised:

- 1) two *keynote addresses* which set the stage for the discussions that followed;
- 2) a "*background/educational session*" which provided participants with the opportunity to learn about basic techniques, terminology and approaches used in socio-economic analysis;
- 3) a session devoted to *presentation of issue papers or case studies*, which highlighted the experiences (both good and bad) of government and industry representatives with respect to development and use of socio-economic analysis;
- 4) a *panel discussion* by participants who worked, or had worked, at the interface between socio-economic analysts and risk management policy experts;
- 5) three *breakout sessions* held in parallel which, in consideration of information provided in Sections 1 through 4 and other types of information, i) identified problems with current approaches for developing and using socio-economic analysis; ii) identified those facets that are particularly effective and should be continued; and iii) made recommendations;
- 6) a *concluding session* in which the results of the breakout sessions were discussed and the final workshop report was developed.

The workshop agreed that socio-economic analysis should be a component, both in the early and later stages of risk management decision making for chemicals, and that OECD should take a leading role in developing, promoting, and assisting in implementing it on a global scale.

A series of recommendations were made with a view to achieving this aim (see the Final Report on the Conclusions and Recommendations from the Workshop). They were considered by the Joint Meeting of the OECD's Chemicals Group and Management Committee in February 1998.

Financial resources to fund the Workshop were provided by the following: the UK Government; Association of Swedish Chemicals Industries; Association of the Dutch Chemical Industry (VNCI); Canadian Chemical Producers Association (CCPA); European Chemical Industry Council (CEFIC); European Chlorine Manufacturers Association (Euro Chlor); Federation of Norwegian Process Industries; (PIL); International Council on Metals and the Environment (ICME); Japan Chemical Industry Association (JCIA); Nickel Development Institute (NiDI); US Chemical Manufacturers Association (CMA); US Council of International Business (USCIB); and Verband der Chemischen Industrie e.V. (VCI) (Germany).

INTRODUCTION

OECD Risk Management Activities

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

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

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

Methodologies and Technical Tools

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

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

The Project on Socio-Economic Analysis

The Risk Management Programme of Work calls for the initiation of activities to provide guidance to the Working Party on Risk Management and others on the use of cost-benefit analysis and any other techniques that can aid decision making in risk management. Experience and expertise should be drawn from work being developed at the national, regional and international levels, and elsewhere within OECD, to develop useful tools to aid decision making. Consideration could also be given to how communication of risks can make the cost-benefit analysis more transparent and can provide a cost-effective alternative to regulatory approaches for reducing risks. The 26th Joint Meeting in June 1997 gave its support to a proposal for a workshop on socio-economic analysis. The UK volunteered to host the workshop.

It was agreed that the best way to initiate this work would be for the workshop to be open to experts in the development and use of socio-economic analysis from around the world. The OECD Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making was organised by the United Kingdom and BIAC (the Business and Industry Advisory Committee to the OECD), in co-operation with Canada, Japan, the United States, the European Commission and TUAC (the Trade Union Advisory Committee to the OECD).

The workshop, which was attended by almost 100 representatives from 18 Member countries, the European Commission, industry and trade unions, was designed to bring together analysts and risk managers to further the integration of socio-economic analysis in chemical risk management decision making by:

- providing basic information on the general techniques, approaches and terminology used in the development and application of socio-economic analysis (i.e. describing what exists and how it is used);
- sharing experiences and identifying expertise; identifying effective techniques and approaches; and highlighting any problems encountered and considering solutions. This would include discussions on: when such an analysis might be appropriate (e.g. in a national, regional or international context); where barriers to its wider use exist and how they may be overcome; and what approaches have been used for valuing costs and benefits;
- identifying areas that need further work within the OECD and Member countries and the means for carrying such work forward.

The UK Government contributed to the funding of the workshop, along with the following BIAC organisations: Association of the Dutch Chemical Industry (VNCI); Association of Swedish Chemicals Industries; Canadian Chemical Producers Association (CCPA); European Chemical Industry Council (CEFIC); US Chemical Manufacturers Association (CMA); Euro Chlor; International Council on Metals and the Environment (ICME); Japan Chemical Industry Association (JCIA); Nickel Development Institute (NiDI); Federation of Norwegian Process Industries (PIL); US Council of International Business (USCIB); Verband der Chemischen Industrie e.V. (VCI, Germany).

PAPERS PRESENTED AT THE WORKSHOP

Making Sense of Risk

John D. Graham

**Director, Center for Risk Analysis, Harvard School of Public Health
United States**

The Psychology of Risk Perception

Cognitive Perspective

People judge the probability of an event by the ease with which they can imagine it or remember relevant instances.

Source: Tversky and Kahnemann, 1974

What Drives the Media?

Media coverage is “driven by rarity, novelty, commercial viability, and drama more than by the concerns about relative risk.”

Comparing Coverage vs. Actual Mortality Risk

“Over-Covered” Risks	About Right	“Under-Covered” Risks
Illicit Drugs	Alcohol	Tobacco Use
Motor Vehicles	Firearms	Stroke
Toxic Agents	Diet	Heart Disease
Homicide	Sex	
	Suicide	

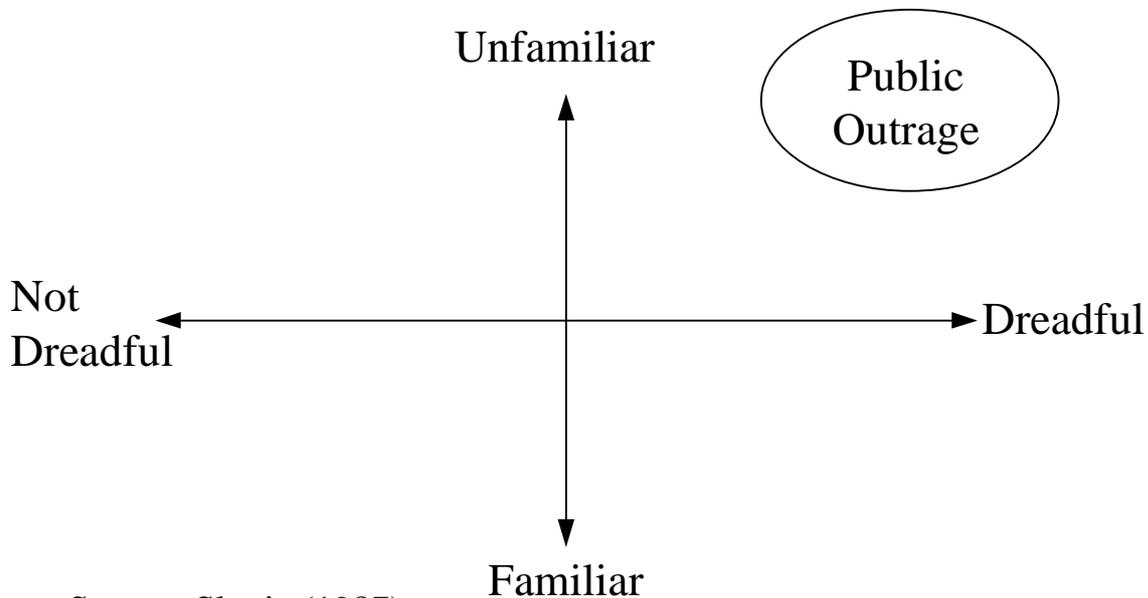
Source: Frost et al (1997)

Outrage Bias

- Attitude: “Better safe than sorry”.
- Examples: Public skepticism of nuclear power, chemicals, agricultural pesticides, biotechnology.
- Exacerbated when danger is salient, beyond individual control, technology is unfamiliar, and costs of prevention are invisible.
- Attitude cultivates useful citizen activism but can misallocate resources.

Sources: Slovic (1987); Margolis (1996)

The Classical Perceived-Risk Model



Source: Slovic (1987)

The Lack of Intuition for Numbers

Numerical Literacy Quiz

Imagine that you face two risks of death but only one can be reduced. Would you rather reduce risk A from 2 in 100,000 to 1 in 100,000 or risk B from 20 in 100,000 to 15 in 100,000?

Numerical Literacy Quiz

Answer: In surveys respondents split evenly, even though the absolute of risk reduction is larger for B (5 in 100,000) than A (1 in 100,000). Reducing risk A has the illusion of superiority because of the larger percentage reduction (50% vs. 25%).

Source: Jonas-Lee et al (1985)

- People have no intuitive feel for small probabilities: 1 in 100,000 versus 1 in 1,000,000?
- People are easily confused about probabilities: one-third of respondents believe that 10 in 100,000 is larger than 5 in 10,000.

Quiz (Disjunctive Events)

Suppose there are 50 independent pathways to an industrial accident in a given year. Suppose managers reduce the annual probability of each path occurring to 0.001 (1 in 1,000). What is the probability of at least one mishap occurring in the next ten years?

Quiz (Disjunctive Event)

Answer ~ 0.40!

$$\begin{aligned} \overline{P} &= [(1-.001)^{50}]^{10} \\ &= 0.606 \end{aligned}$$

Note: Most people underestimate the chance of disjunctive events

Quiz: Conjunctive Events

$$P = (0.33)^{10} = 0.000015$$

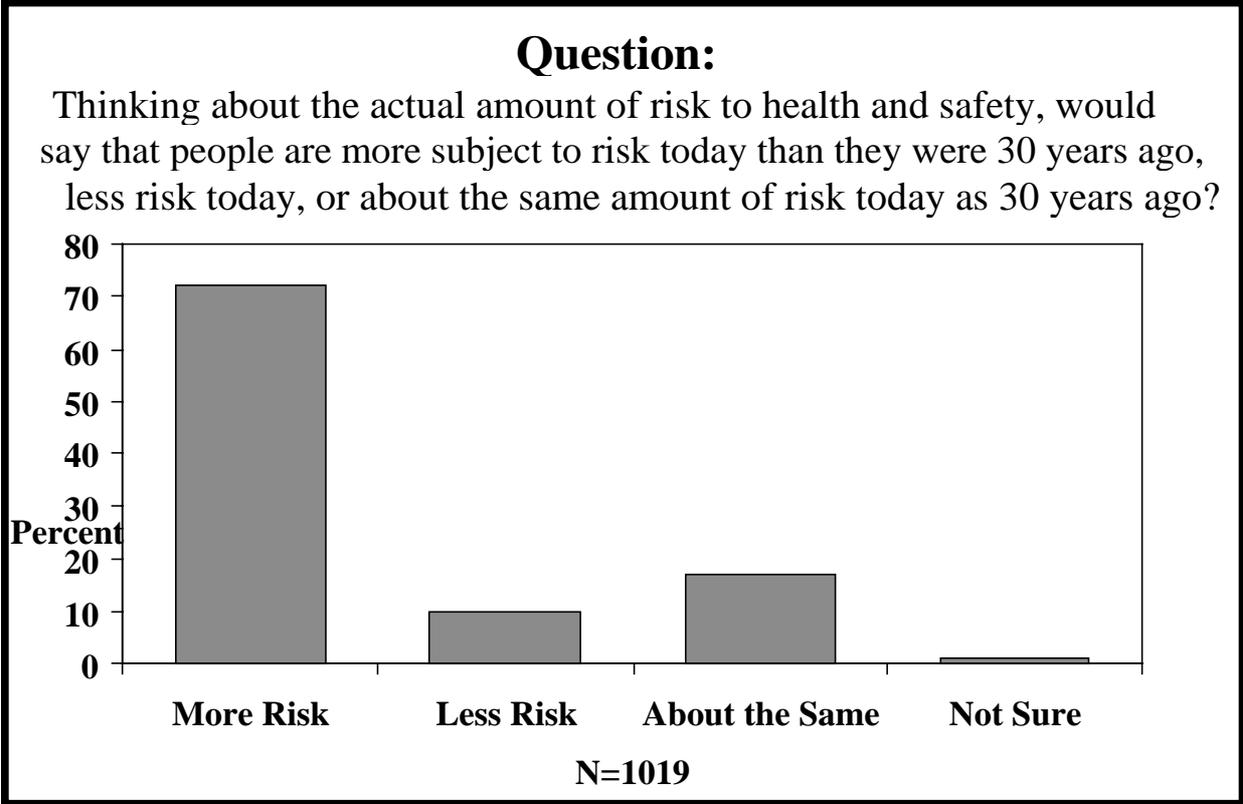
(less than 1 chance in 50,000)

Note: Most people overestimate the probability of conjunctive events

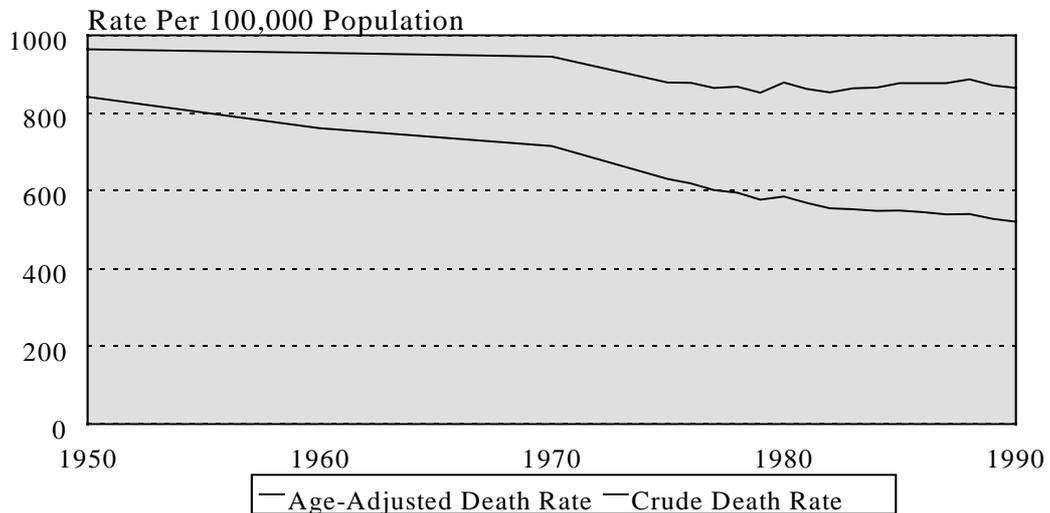
People Have Sensible Value Positions About Outcomes

- Fatal hazards are worse than nonfatal hazards.
- Involuntary hazards are worse than voluntary hazards.
- A death to a random child is worse than a death to a random senior citizen.
- Multiple deaths at the same time and place aren't much worse than the same number of deaths at different times and places.
- Concentrating risk on a small group is worse than spreading the same amount of risk over a large group.

Public Perceptions and Misperceptions of Risk



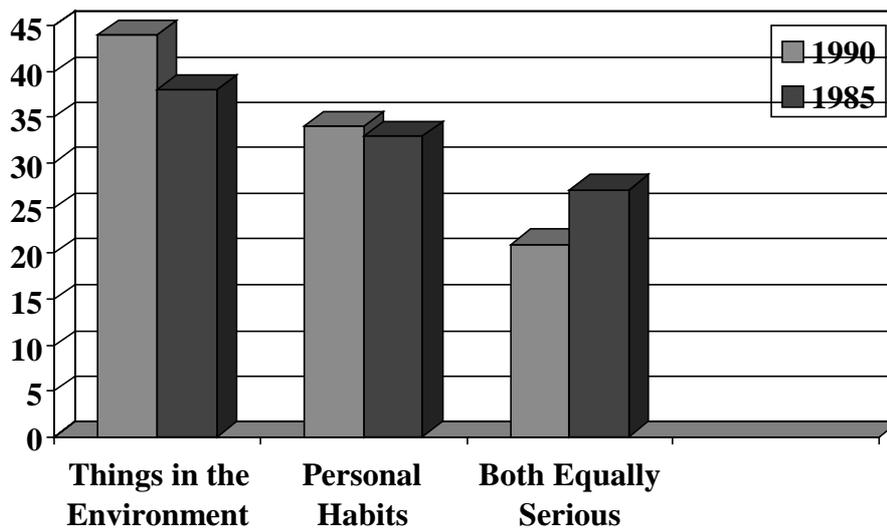
CRUDE AND AGE-ADJUSTED DEATH RATES, U.S., 1950-1990



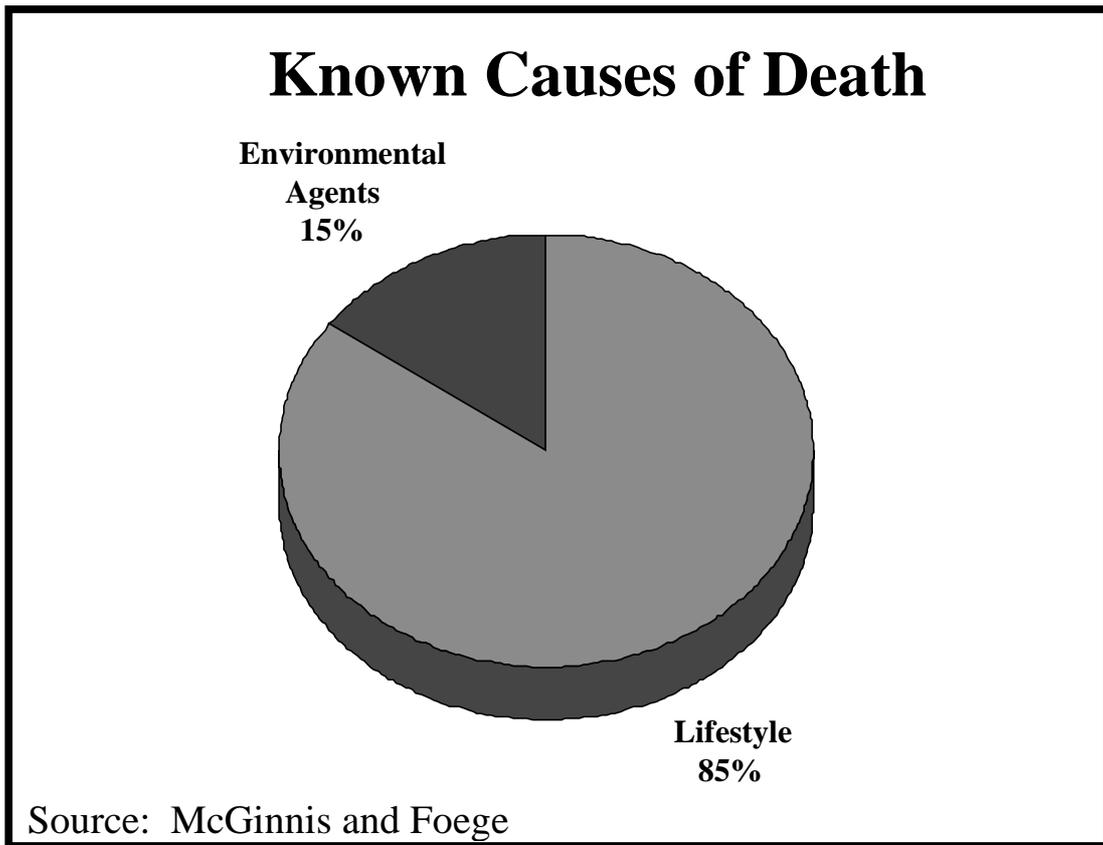
Source: CDC (1993)

Question:

Which one do you think is most serious in this country today in terms of causing health problems for people?



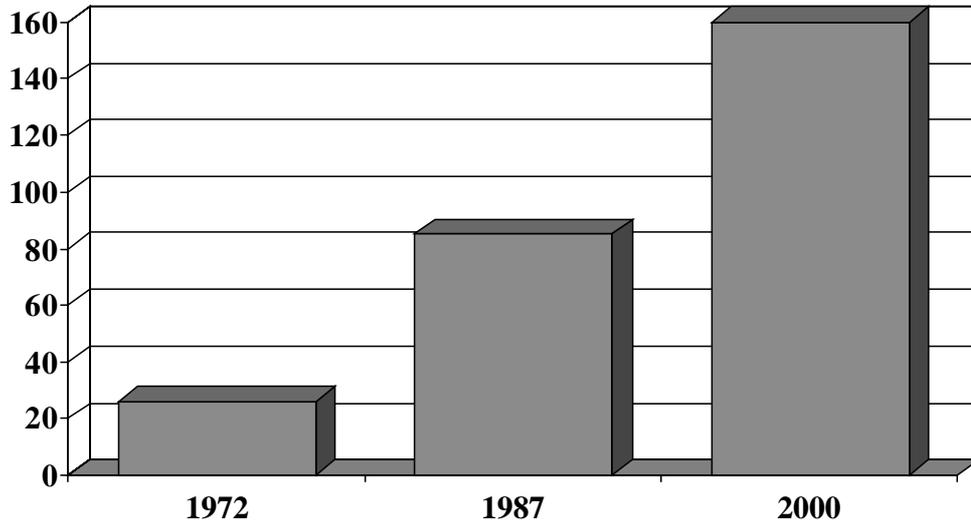
Source: Roper (1990)



Which is More Likely to Increase Cancer Risk?

	<u>Males</u>	<u>Females</u>
Pesticide Residues on Fruits and Vegetables	53.8	59.1
Too Few Fruits and Vegetables	41.3	36.0
Other/DK	4.9	4.9

**Estimated Cost of Pollution Control,
1972-2000, USA**
(Billions of 1990 \$)



Source: EPA (1990)

**Senator Daniel Patrick
Moynihan**

\$150 billion per year is not necessarily too much to invest in environmental protection but it is surely too much to invest unwisely.

Emerging Risk Issues

- Global warming
- Electric and magnetic fields
- Fine particles in the air
- Endocrine-disrupting chemicals
- Multiple chemical sensitivity

**Advocate the Risk Analysis
Framework!**

Steps Toward Solution

1. Require Objective Risk Assessments Based on the Weight of the Evidence.

Common Flaws in Risk Assessment

- hidden assumptions
- implausible assumptions
- assumptions instead of data
- poor quality data
- selective use of data
- downplay “protective” effects
- forget sensitive people
- preoccupation with cancer
- report only worst case
- technical mumbo-jumbo

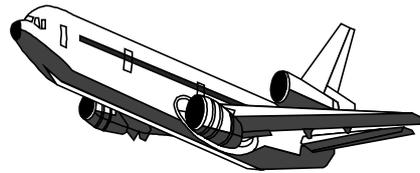
2. Quantify Risks and Provide Perspective

Question:

What is a newborn's chance in his or her lifetime of being killed on the ground by a crashing airplane?

Answer:

4 in a million



Source: Goldstein, et al 1992

3. Rank Risks in Order of Priority

Which Item Kills More People in the USA each year?

	<u>Sex</u>	
	<u>Males</u>	<u>Females</u>
Traffic Crashes	74.2	53.1
Bullets from Handguns	24.9	44.1
Other/DK	0.9	2.8

Which Item Kills More People in the USA Each Year?

	<u>Sex</u>	
	<u>Male</u>	<u>Female</u>
Air Pollution Outdoors	55.6	68.0
Air Pollution Indoors	41.5	28.3
Other/DK	2.9	3.7

Potential Gains from “Rational” Priorities

- Save 60,000 more lives per year at no increased cost to taxpayers or the private sector!

OR

- Save the same number of lives we are now saving but at an annual savings of \$31 billion!

Source: Tengs et al (1995) based on a sample of 205 policies.

Beyond “Lives Saved”

- Expected Life Years (ELYs)
- Disability-Adjusted Life Years (DALYs)
- Quality-Adjusted Life Years (QALYs)
- Decently Livable Life Years ??

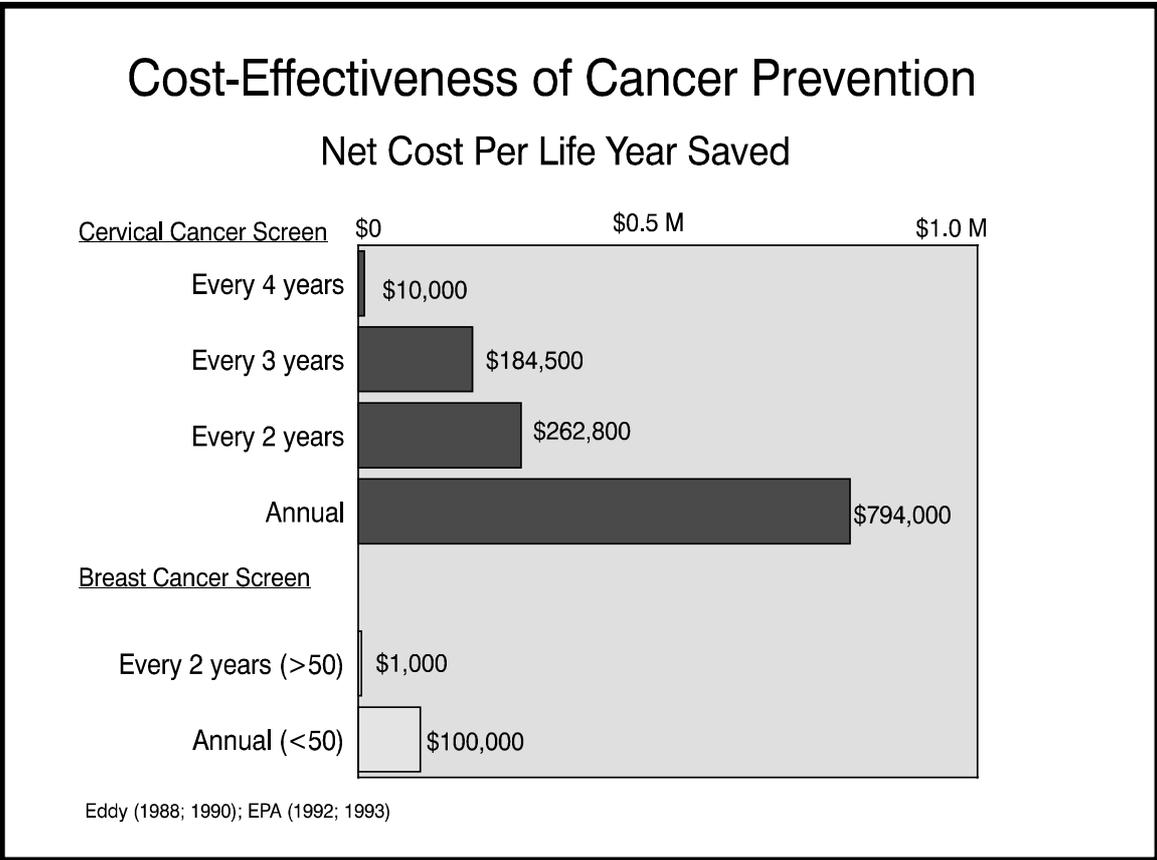
4. Weigh “Countervailing Risks” as well as “Target Risks”

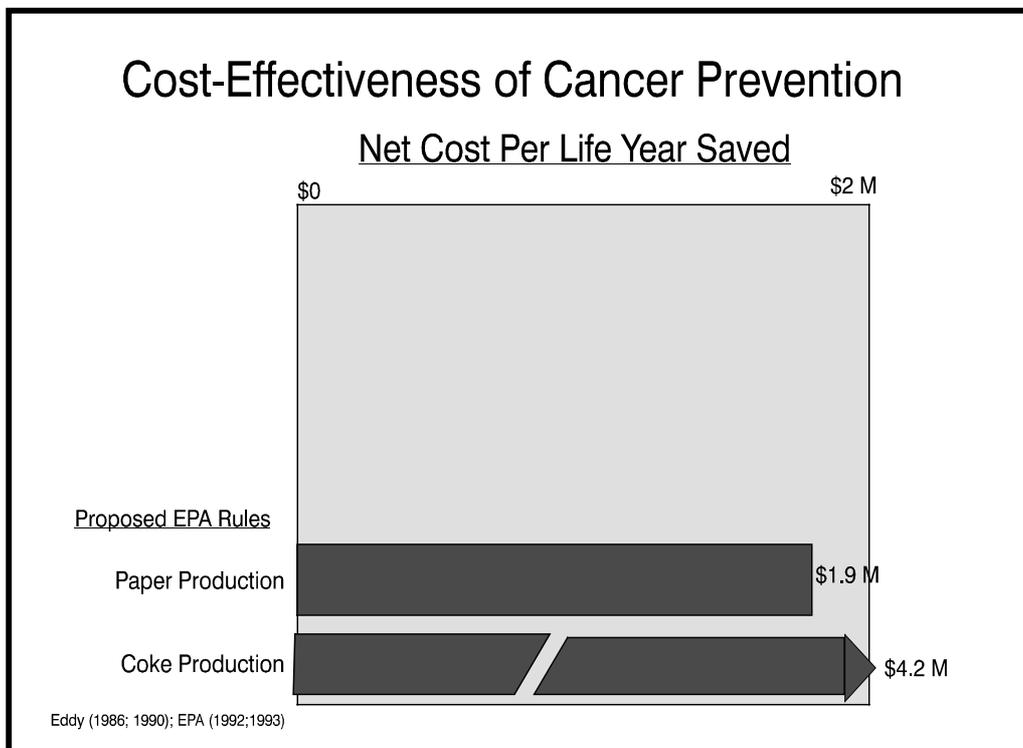
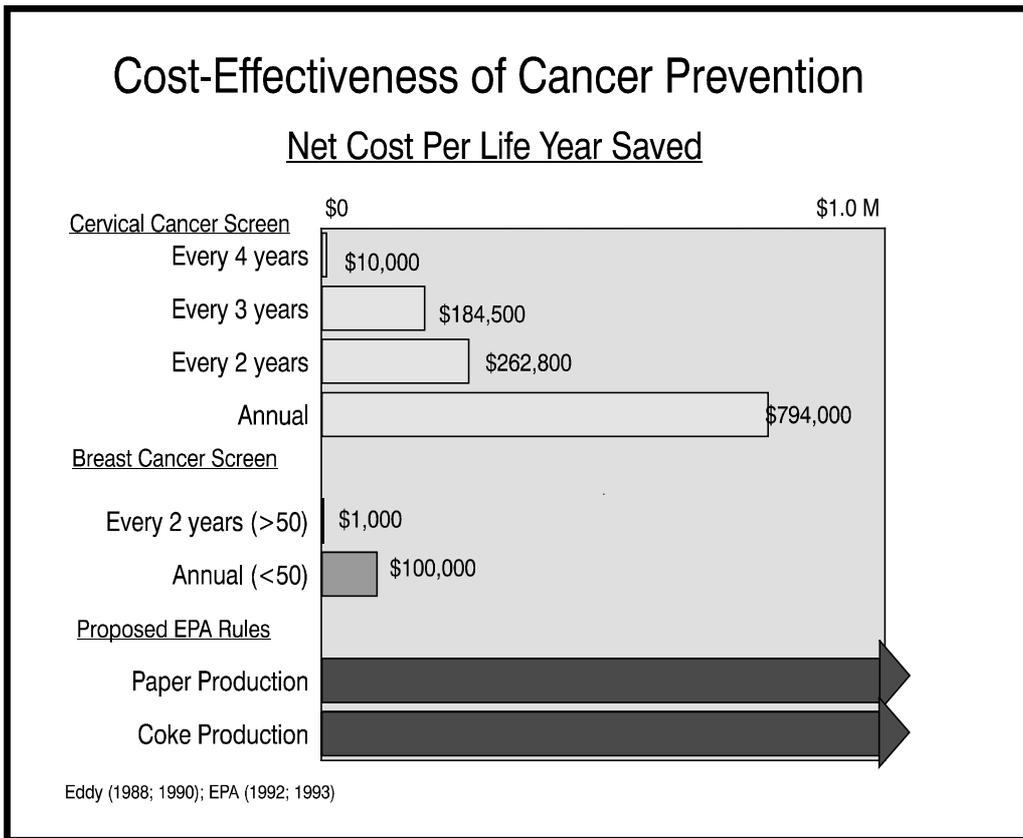
Airbag Benefit-Risk Ratios

	Driver Airbag	Passenger Airbag
Lives Saved/ Lives Lost	70	10
Life Years Saved/ Life Years Lost	70	5

Source: NHTSA (1996); Graham et al (1997)

5. Balance Incremental Costs Against Benefits





$$\text{CE ratio} = \frac{C_g - C_s}{Y}$$

C_g = gross costs

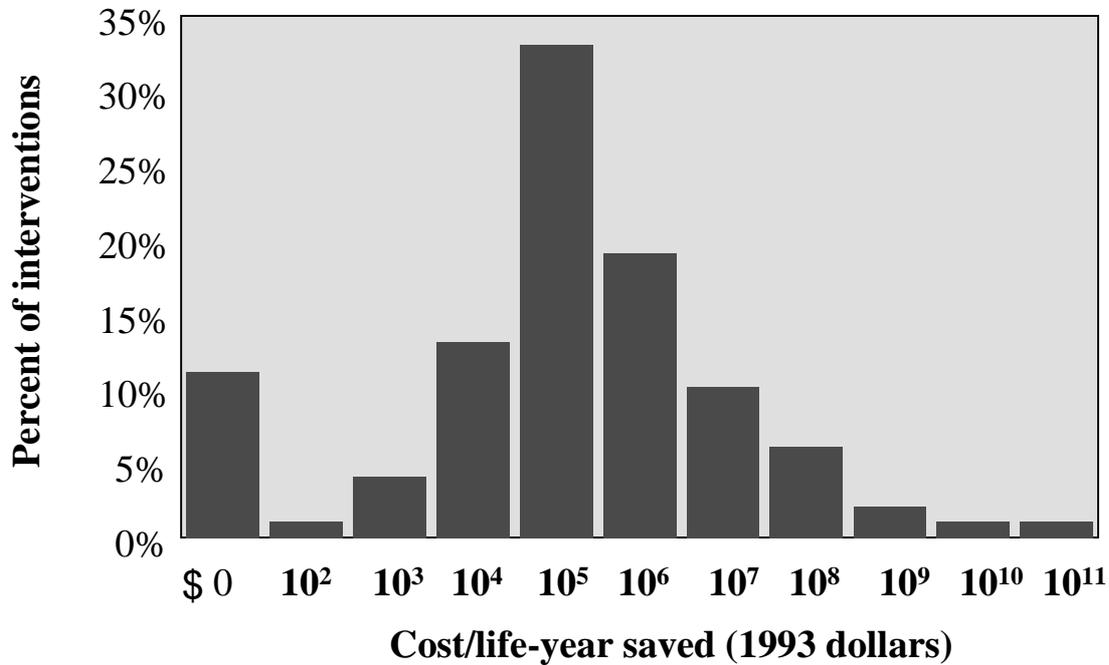
C_s = resource savings

Y = life years saved

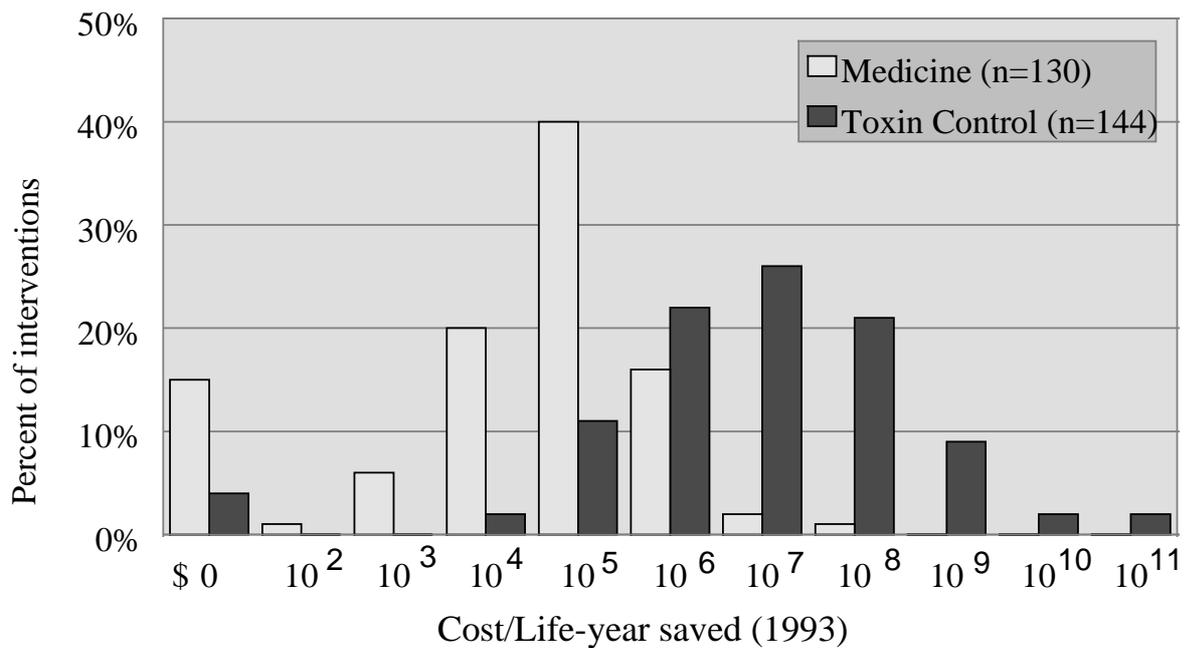
EXAMPLES WHERE BENEFIT-COST ANALYSIS SUPPORTS REGULATION!

- ✓ airbags (NHTSA)
- ✓ chlorofluorocarbons (EPA)
- ✓ unleaded gasoline (EPA)
- ✓ beta-blockers (FDA)
- ✓ childhood immunizations (CDC)
- ✓ ATV's (CPSC)
- ✓ break-away sign posts (FHA)
- ✓ targeted lead paint abatement (HUD)

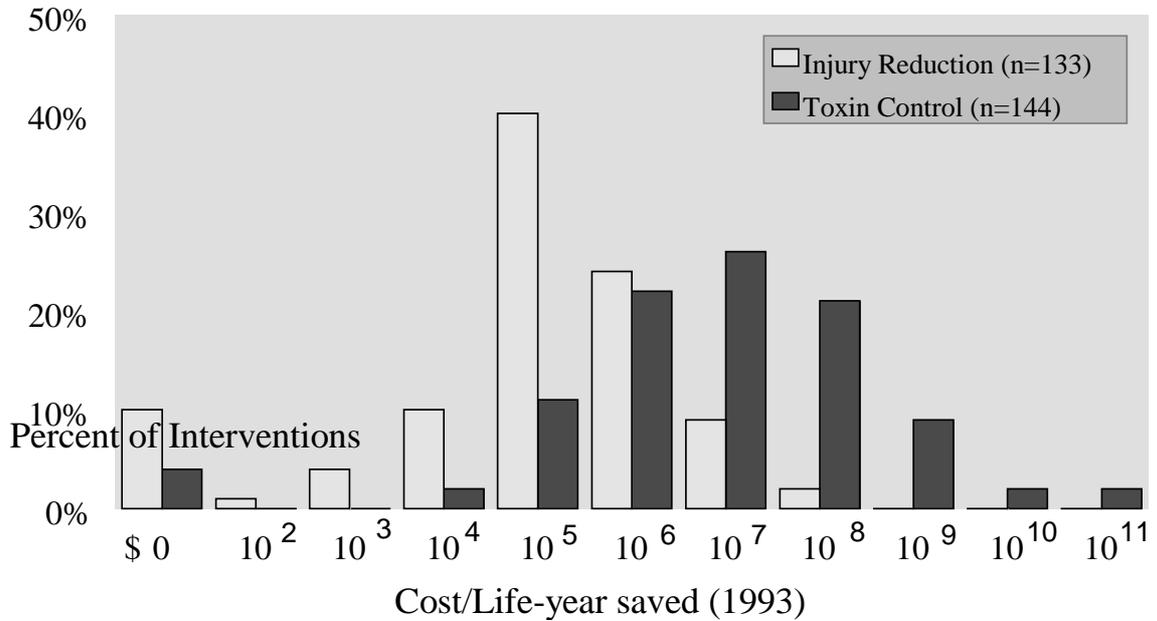
Cost/Life-Year Saved Distribution



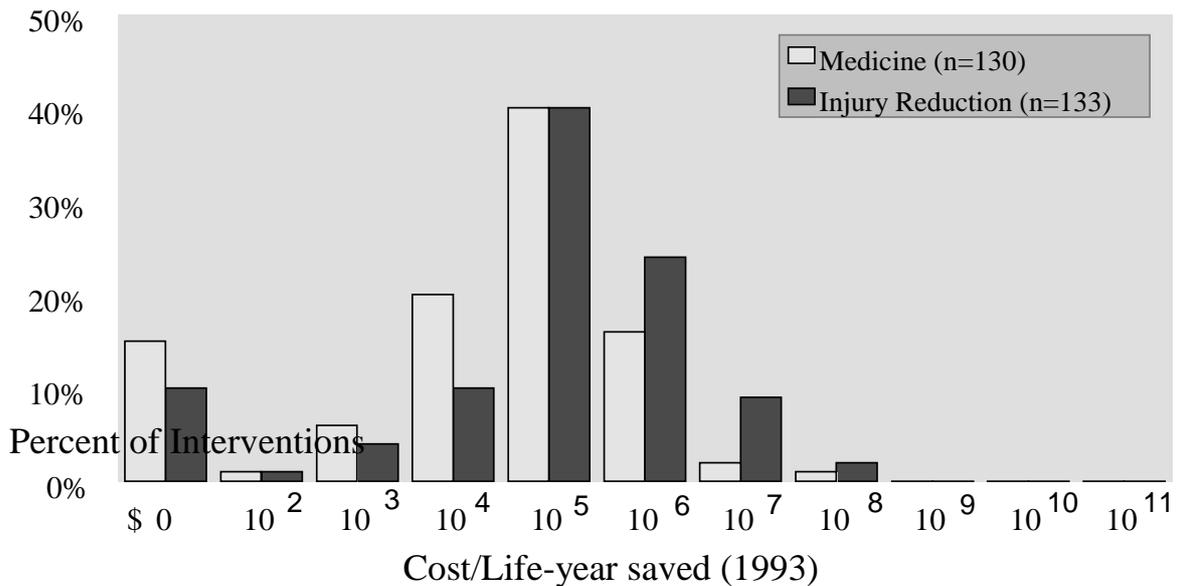
Cost/Life-Year Saved Distributions: Medicine vs. Toxin Control



Cost/Life-Year Saved Distributions: Injury Fatality Reduction vs. Toxin Control



Cost/Life-Year Saved Distributions: Medicine vs. Injury Fatality Reduction



Price of Reform: Analytical Resources

- Build staffs of Agency
Scientists/Economists
- Cultivate Elite Career Path in Civil
Service at OMB/OSTP (Breyer proposal)

One Final Request

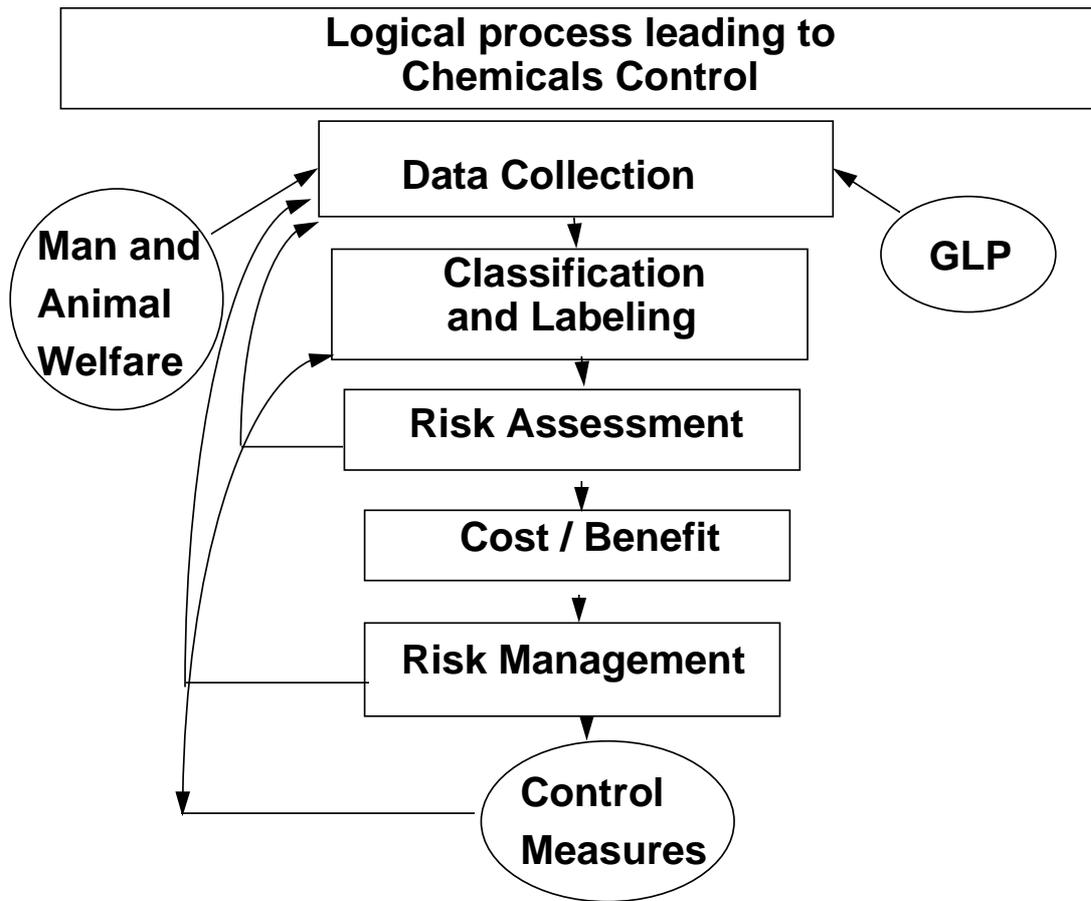
**Ultimate Goal: More Public
Protection at Less Cost!**

Introduction to Risk Assessment of Chemicals: Basic Principles

**Henri de Henau, Tom C.J. Feijtel and C.C. Lally
Proctor and Gamble - Europe**

Who is using Risk Assessment ?

- **Used by Agencies and regulators for setting human and environmental health policies.**
- **Used by Industry to assess risk implications of the production, formulation, use and disposal of chemicals and products.**
- **Used by Industry and Agencies to identify further data and/or research needs.**
- **Applied by Industry and Agencies in decision making process (Risk Management).**
- **Used to communicate risk science information to public.**



Definitions - Hazard/Risk

Hazard identification:

To identify the effects of concern. The term hazard can be explained as "the potential for causing adverse effects to humans or ecological systems" (Calow 1993), and attempts to characterize the intrinsic properties and toxicity of a substance. In transport, storage and occupational safety hazard is classified into classes of severity which are used for the purpose of safety labeling.

Risk Assessment:

The goal of a comprehensive risk assessment is to estimate the likelihood and the extent of an adverse effect occurring in man, animals or ecological systems from possible exposure(s) to chemical or physical agents.

The process of Risk Assessment

- According to US Academy of Sciences, the process of risk assessment comprises 4 steps :
 - ◆ hazard identification
 - ◆ dose/response assessment
 - ◆ exposure assessment
 - ◆ risk characterization
- These 4 steps have also been adopted by the EU and are captured in the Technical Guidance Documents for Risk Assessment of New and Existing Substances

Hazard identification & characterization

- It is the characterization of the intrinsic toxic potential, also described as the inherent toxicity property.
- Proceeds in a stepwise system, where the need to continue refining the hazard identification is triggered by the estimated human safety margin or environmental risk.
- Toxic potentials are typically determined using internationally agreed test methods.

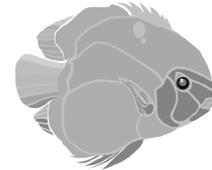
Human Health Hazard

- Various in vitro tests are screening tools to determine some effects (e.g. mutagenicity) or to investigate specific elements of an endpoint in isolation (activation mechanism).
- In vivo animal toxicity studies can be acute, sub-acute, sub-chronic or chronic. Their duration aims at reflecting the predicted exposure to man. Objective is to develop dose response curves.
- Test species are selected to optimize relevance to man. Both sexes are investigated in statistically appropriate size groups. Most relevant exposure route is selected.
- Metabolic studies are common to develop understanding of mode of actions.
- Clinical trials are used for some substances.
- In vivo tests are usually operated at doses much higher than those to which man might be exposed. Mathematical models are used to interpret dose response curves in the low dosage ranges.

Environmental hazard

- **Single species laboratory tests provide a screening tool to detect the intrinsic toxicity profile of a chemical (acute, subacute or chronic) . Experiments are conducted on most sensitive species, representative of different trophic levels. This typically include, bacteria, algae, daphnids, fish. They may also include earth worms, higher plants when soil exposure is a concern. More rarely birds, particularly when bioaccumulation along the food chain is suspected.**
- **Uncertainties in the derivation of safe levels from single species exist (intra and inter species variations, short term long term toxicity extrapolations laboratory to field extrapolation. These are coped with by using application (extrapolation) factors.**
- **At higher tier testing, mesocosms research and field studies may play an important role to refine the prediction of PNEC's of ecosystems.**

For Example: Uncertainties in the derivation of PNEC Principles

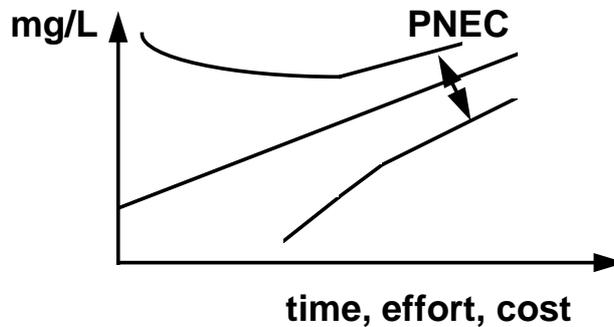


- 1/ To ensure adequate protection of organisms in the environment, toxicity data should be collected for sensitive species.**
- 2/ The distribution of species sensitivity to any given compound is often not known.**
- 3/ Species sensitivity has been compared for a wide variety of compounds and species . “Daphnids, trout, and minnows are generally considered as sensitive species” (OECD, 1994).**
- 4/ For a same species, toxicity test results are affected by dilution water, temperature, organism factors such as health, diet, crowding, and reproductive and disease status, and experimental factors such as measurement of test concentrations, statistical methods, and test duration. Standardization is important to reduce this uncertainty.**
- 5/ The predicted no effect concentration has been shown to be dependent on the type and amount of data, and the assumption of the calculation methods used.**

Uncertainties in the derivation of PNEC Practice

- Justification for stepwise or tiered approach to derive the PNEC's comes from the initial use of sensitive species in the lab which lead to conservative assessments relative to more ecologically relevant mesocosm and field testing.
- Continuing to collect higher levels of data to reduce uncertainty goes often in parallel with the finding of higher PNEC values than predicted.

Uncertainties around the derivation of the PNEC remain even at higher tiers and are difficult to accurately quantify.



Risk to man

- Based on the comparison of the measured or predicted exposure dose for a specific target group or sub-population of concern with a no observed adverse effect (NOAEL), generally derived from experimental animal studies.
- The ratio between the NOAEL and the exposure estimate is often referred to as the margin of safety. It must be sufficient to account for the species differences (extrapolation animal to human) and variability in the human population.
- Confidence increases with more relevant toxicity data becoming available, allowing one to understand toxic action and their relevance to man.

Risk to the environment

- **Based on the comparison of the measured or predicted environmental concentration (PEC) of the chemical with the predicted no effect concentration (PNEC) to organisms in that ecosystem.**
- **PNEC is derived from extrapolation, using application factors, of acute and or chronic single species laboratory data. Confidence increases (smaller extrapolation factors) if more relevant data are available from different taxonomic groups with different feeding strategies and tested at most relevant conditions (time, location, attributes).**

Commonalities and Differences between Human and Environmental Risk Assessments

- **For both human and environmental risk assessments, measured or estimated exposure levels are compared with a concentration or dose which, taking into account adequate assessment factors, is regarded as safe.**
- **In Human risk assessments, application factors are not defined and will vary depending on data availability, test duration, number of species tested. Understanding modes of actions is important.**
- **In Environmental risk assessments the uncertainties are accounted for by agreeing on application factors to predict PNEC's. Mode of action is not taken into account.**

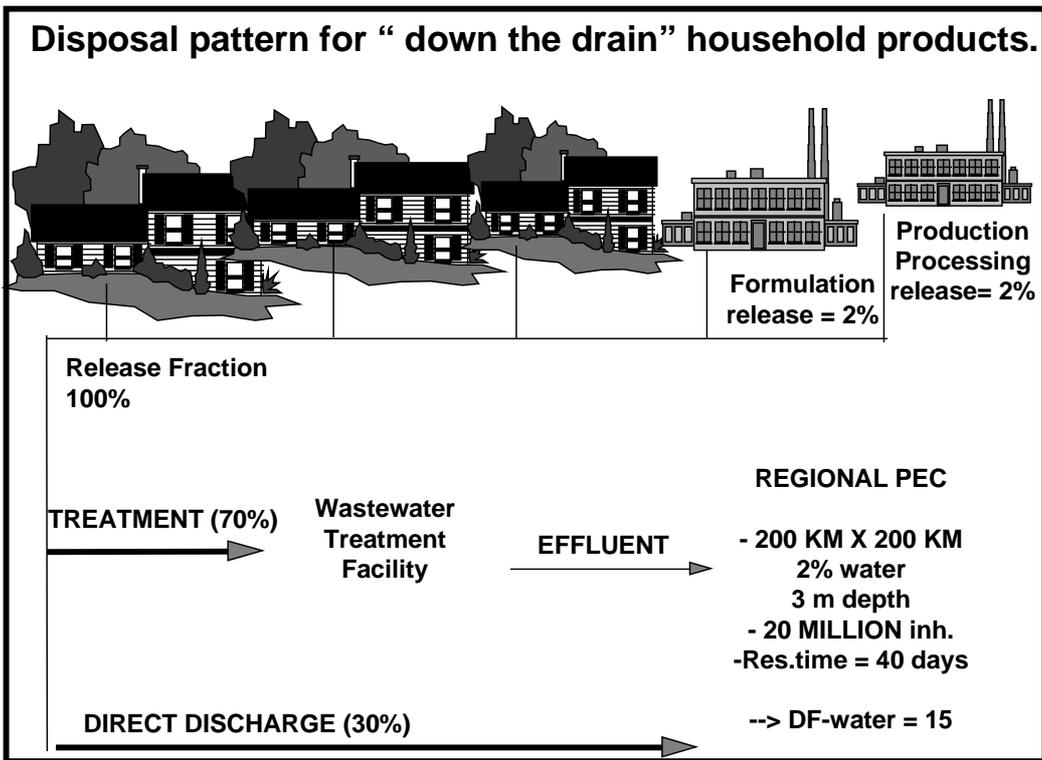
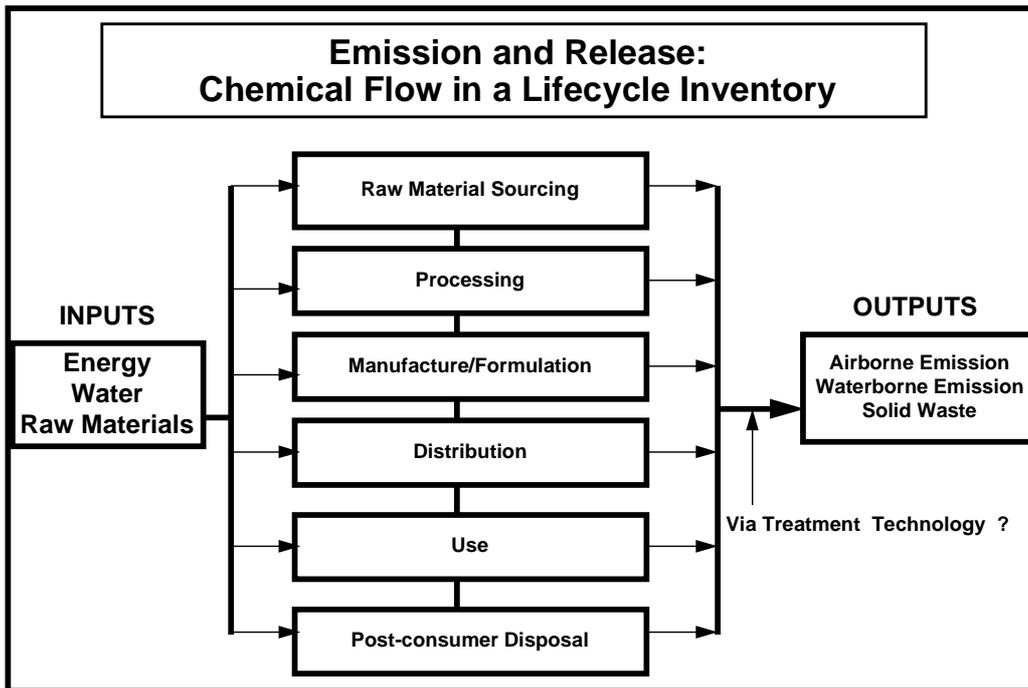
Human Exposure

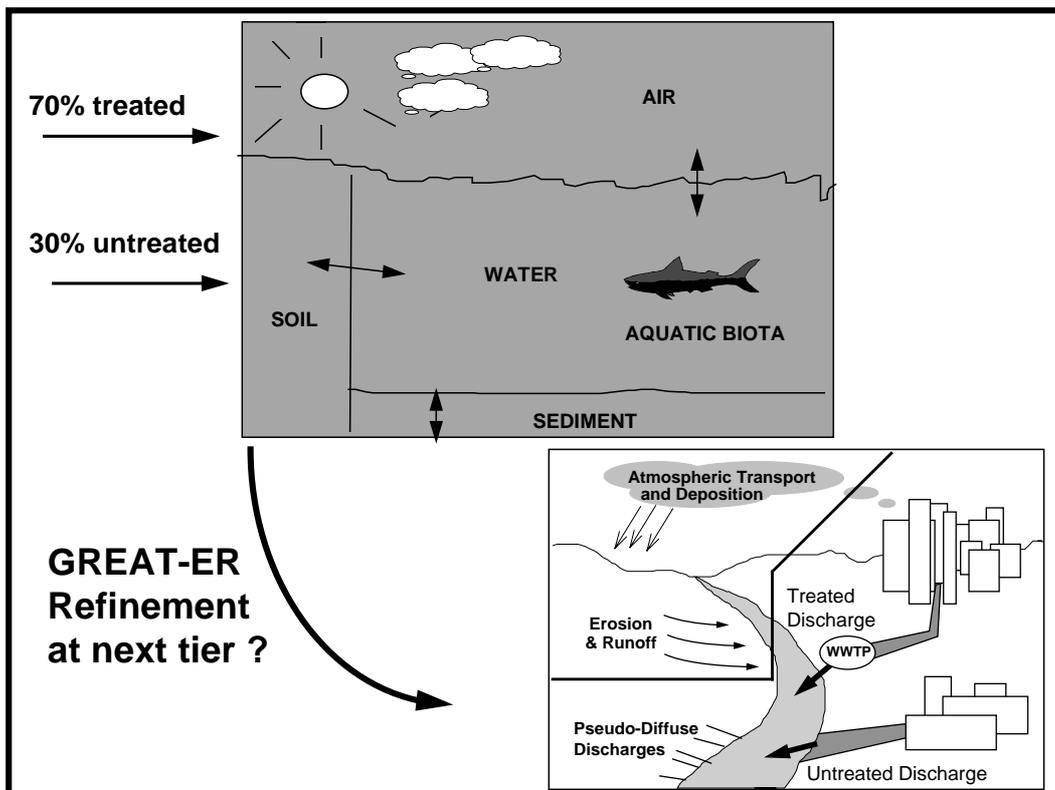
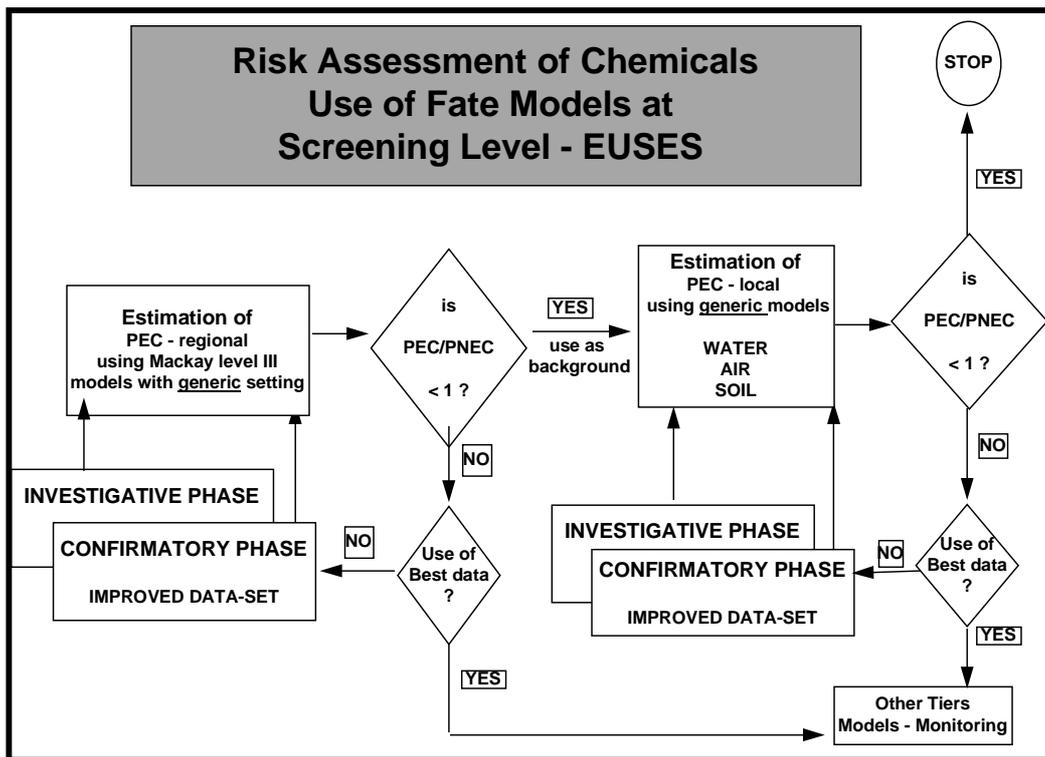
Is exposure to man likely to occur ?

- **Who is being exposed ?** Definition of the target exposure in terms of number of individuals, average individual, sub sets of individuals, individuals with known sensitivities.
- **Mode of exposure ?** Determine variability, duration, frequency.
- **Route of exposure ?** oral, dermal, inhalation. This will impact on test design and contribute to reducing uncertainties of R.A.
- **Use of data bases** documenting any given use scenario. Although well documented in some areas, a subject where substantial progress is desirable.
- **Link with Environmental exposure to determine indirect human exposure via the environment. (inhalation, ingestion, dermal contact)**

Environmental Exposure

- **What is the primary target of the exposure assessment, what is being exposed and for how long (point source versus diffuse and intermittent versus continuous emissions)?**
- **Local worst case estimates at point of emission.**
- **Local realistic worst case estimates.**
- **Regional background estimates after fate, transport, distribution mechanisms have taken place.**
- **Generic and detailed description of receiving environments.**
- **Emission scenario considering full Life Cycle.**



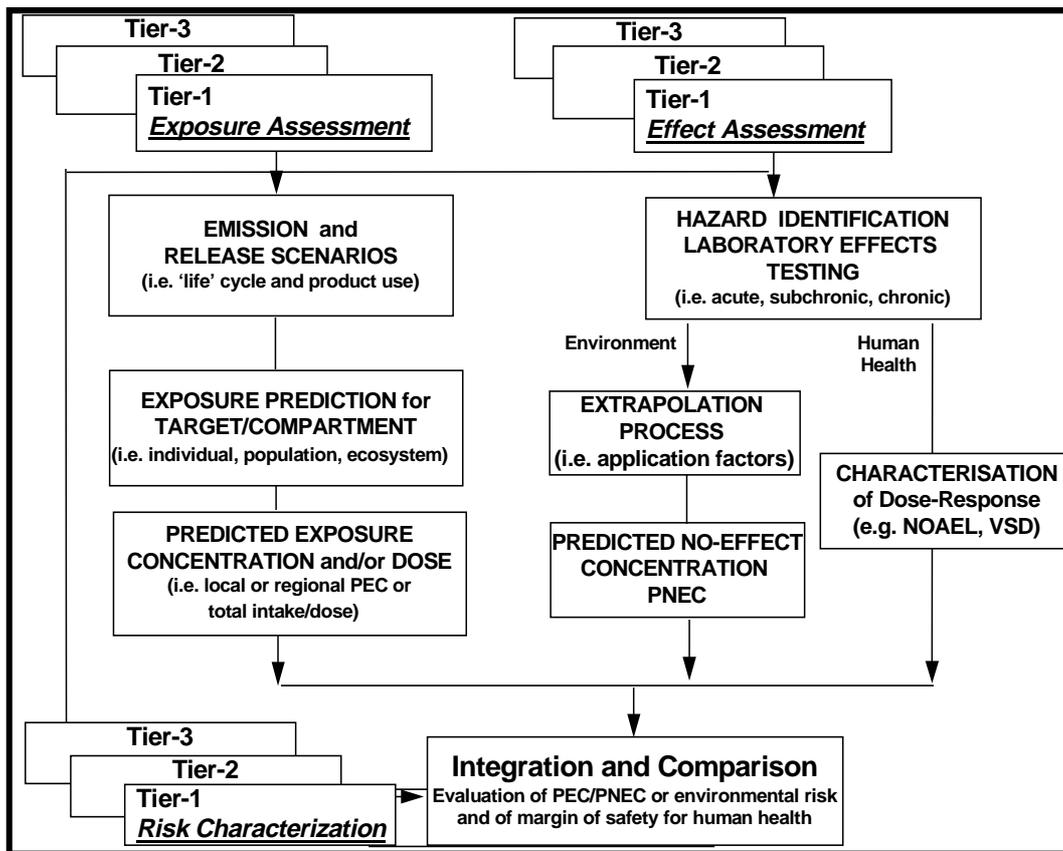


Human health risk characterization

- For Human health risk, the NOAEL and exposure are critically compared.
- Margins of safety should incorporate adjustment factors to take into account interspecies variations and uncertainties related to the exposure pattern.
- Information on toxicokinetics will allow to refine acceptable safety margins.

Environmental risk characterization

- For Environmental risk assessment, PEC's are critically compared to PNEC's.
- Predicted no effect concentration (PNEC) uses established extrapolation schemes based on application factors.
- Aqueous concentrations are regarded as surrogate to the concentration at the target site of the organism. Uncertainties associated with the predicted exposure and its bioavailability to the target organism need to be addressed.
- The concept of "Critical Body Residues" to replace current endpoint concentrations may bring closer together environmental and human health risk assessments.



Conclusions

- A step-wise or tiered system has been adopted for both the environmental and human health risk assessments, as the most cost effective approach. It allows to allocate resources to the highest priority compounds and/or allows focus on critical endpoints or exposure parameters.
- This step-wise RA process has a history of success. However it needs further refinement, particularly to validate assumptions and default values at the first screening level. Overly conservative assessments are counter-productive and very costly.
- Further insights into the limitations of the assessment and quantification of uncertainties are needed, particularly around the exposure estimates
- Variability of human parameters and of receiving environments need to be better documented.

The Integration of Socio-Economic Analysis in Chemical Risk Management: An Overview

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Introduction

The widespread use of chemicals in modern society has led to increasing concern over the potential effects of certain substances on both people and 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. In some cases, the potential risks associated with use of a particular substance have warranted action at a global level in order to reduce documented environmental and/or human health effects.

However, such actions are not without costs, where these may include production costs to industry and thus higher end-product costs to consumers. The substitute chemicals may not be risk-free either, but instead lead to a shift in the nature of risk (e.g. from acute to chronic effects, or from human health effects to the environment). 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 greatest risks. It is important that a balance is struck between the costs involved in reducing risks and the benefits stemming from risk reduction.

The aim of this paper is to provide an overview of the use of socio-economic analysis in assisting decision makers to reach a balance between the risks, costs and benefits associated with chemical risk management. The paper starts by identifying the potential appraisal approaches which could be adopted for the socio-economic analysis. It then provides a brief summary of current practice within OECD Member countries. An assessment framework is then proposed based on the principles of cost-benefit analysis, and the application of this framework to the estimation of impacts on industry, the wider economy, human health and the environment is then reviewed. The paper finishes by identifying a set of issues which should be addressed as part of the development of internationally agreed guidelines. These issues relate both to the context within which such analyses are undertaken and the nature of the analyses themselves.

The Policy Context

There is a growing international consensus on the importance of comparing the risks, costs and benefits of specific applications of chemicals against those associated with the use of substitutes as part of the risk management process. For example, in 1990 the OECD Council Act on Co-operative Investigation and Risk Reduction formally established the Risk Reduction Programme. In 1996, this Programme became the OECD Risk Management Programme which now gives preference to the problematic uses of a chemical rather than to the chemical in all applications. In addition, a common risk management process appears to be emerging at an international level, similar to that set out by the OECD Advisory Group on

Risk Management. This Group has recognised that some form of analysis is required which weighs up the advantages and drawbacks of each proposed option in order to determine which is preferred.

Although the specific requirements and hence nature of an analysis may vary over different regulations, there is a general recognition that it may take one of three possible forms (DoE, 1995):

- a systematic qualitative assessment;
- a semi-quantitative assessment, where some aspects of the risks, costs and benefits are assessed in quantitative terms while others are treated qualitatively; and
- a fully quantitative assessment, where all risks, costs and benefits are quantified.

In some cases, a qualitative assessment will be sufficient in indicating how the benefits to human health and the environment compare with the costs to producers and other stakeholders; for example, where the risks are obviously high and unacceptable. In other cases, a qualitative assessment will not be detailed enough to show whether the benefits from improved safety outweigh the costs. As a result, more quantified assessments are likely to be required.

It should be possible for most regulatory issues to develop estimates of the costs involved in adopting and implementing a risk reduction option. Similarly, many of the economic benefits associated with the use of a chemical to producers and other stakeholders may be readily calculated. For proposals which are likely to have significant resource implications, a fully quantitative assessment is likely to provide the most robust information. Where both quantification and monetary valuation are possible, the expression of environmental and human health benefits in the same units (money) as the costs of control allows direct comparisons to be made and thus the merits of the proposed regulation to be more readily evaluated. This should also help improve the consistency of decision making.

Table 1 overleaf illustrates why quantification can be important. It shows how widely varying the implicit values placed on human health and safety can be in the absence of a fully quantitative, monetary analysis. The table draws on some examples from recent US risk reduction regulations. Of these examples, only for the regulations set by the US Department of Transportation were the potential costs and benefits associated with reductions in transport risks examined prior to the setting of new safety measures (Belzer, 1992). In the other cases, the costs of control did not enter into the analysis of different options and the implied valuations vary by several orders of magnitude.

Social cost-benefit analysis (CBA) provides a framework for undertaking fully quantitative analyses and provides a rational means for weighing the advantages and disadvantages of alternative regulatory options. As the aim of CBA is to determine whether an investment is worthwhile from a social perspective, it extends beyond financial analysis, which examines only private costs and benefits (i.e. a company's profit and loss account). Instead, it is aimed at assessing all of the effects of a policy or project and valuing them in economic resource or opportunity cost terms, where these include human health, environmental and other social costs and benefits. In economic terms, the most efficient option is then defined as that which provides the greatest level of well-being for society as a whole. An option is justified if the benefits of action outweigh the costs. When a series of risk reduction options are being considered, the option with the highest ratio of benefits to costs (assuming benefits outweigh costs in all cases) is that which is most preferred.

There are likely to be a number of cases, however, where it will not be possible within a given analysis to derive monetary values for all of the social costs and benefits associated with a decision. Such

difficulties arise where there is a lack of scientific data or where there are process and methodological difficulties in deriving valuations owing to the nature of the risks and impacts. For example, it may be accepted that a particular chemical poses a risk to a marine species, but owing to a lack of information on the populations at risk (due to a paucity of data on environmental concentrations, for example, or on numbers within a population), it is impossible to quantify the magnitude of any impacts. In addition, there may be problems in deriving economic values for damages to a particular species or habitat if it is not of commercial value or one which is easily recognised and well understood by the public.

In such cases, it may be necessary to draw on the use of other assessment tools. **Cost-effectiveness analysis** is probably the most commonly used alternative to CBA. This form of analysis can be used to determine the most cost-effective means of achieving pre-set targets or goals (such as those associated with levels of “acceptable” risk as set out in government guidelines). Where agreed targets do not exist, cost-effectiveness analysis can be used to look at the implicit value which would have to be placed on a level of risk reduction in order for action to be justified. For example, in the case of human health risks, an indication could be provided on the costs per cancer case avoided.

However, where a number of adverse effects may occur (e.g. both human health and environment related), the analysis will be less straightforward and implicit valuations must somehow be apportioned between the different effects. This problem is likely to arise for many chemical substances. In addition, different options are likely to lead to varying levels of control, with some options meeting targets while others fall short but involve significantly lower costs. The main drawback to cost-effectiveness analysis, however, is that it does not automatically address the question of how much society is willing or able to pay to obtain reductions in risk. As a result, it provides no direct indication of whether the benefits outweigh the costs, only that the goals as defined are met.

Multi-criteria techniques can provide the basis for preparing a semi-quantitative (or qualitative) assessment. These techniques are similar to CBA in that they provide a means of converting information on impacts into a common unit of measurement to allow direct comparison of alternative measures. The techniques vary in sophistication, ranging from simple scoring and weighting systems to more complex approaches based on the use of formal procedures for eliciting values and intricate mathematical operations. Although they have seldom been used as part of regulatory decision making, there are a number of experts who believe that further consideration should be given to their use as an alternative to CBA (Gregory & Slovic, 1997).

Use of Socio-economic Analysis

The use of CBA and other assessment approaches is an established part of regulatory decision making, although such analyses are more common in some policy areas than in others. For example, CBA is often applied to policies concerning nuclear safety, transportation safety, flood and coastal defence planning, air quality, water resource management, etc. Table 2 sets out the extent to which OECD Member countries apply or require the application of CBA and other assessment approaches as part of regulatory decision making. As the table indicates, all countries require some form of regulatory impact analysis, with a large number drawing on both CBA and cost-effectiveness analysis as the basis for such assessments. It is likely, though, that the level of application across the different countries varies widely in terms of both comprehensiveness and the reliability of results.

Table 1: Implied Valuations of US Risk Management Regulations (US\$ M)

Regulation	Cost a Factor in Decision Making?	Year Issued	Health or Safety	Mortality Risk per Million Exposed	Cost per Premature Death Averted (\$M)
<i>Aircraft Cabin Fire Protection Standard</i>	<i>Yes</i>	<i>1985</i>	<i>Safety</i>	<i>5</i>	<i>0.1</i>
<i>Aircraft Seat Flammability Standard</i>	<i>Yes</i>	<i>1984</i>	<i>Safety</i>	<i>11</i>	<i>0.4</i>
<i>Children's Sleepwear Flammability Ban (LE 12)</i>	<i>No</i>	<i>1973</i>	<i>Safety</i>	<i>29</i>	<i>0.8</i>
<i>Benzene NESHAP Fugitive Emissions</i>	<i>No</i>	<i>1984</i>	<i>Health</i>	<i>1,470</i>	<i>3.4</i>
<i>1,2 Dichloropropane Drinking Water Standard</i>	<i>No</i>	<i>1991</i>	<i>Health</i>	<i>NA</i>	<i>653.0</i>
<i>Hazardous Waste Listing for Wood Preserving Chemicals</i>	<i>No</i>	<i>1990</i>	<i>Health</i>	<i><1</i>	<i>5,700,000</i>

Cost per premature death averted \$M 1990
70 year lifetime exposure (LE) assumed unless stated.
Source: Belzer, 1992

Table 2: Type of Appraisal Applied to Environmental Regulations by Country

Country	Cost Only	Cost-effectiveness	CBA	Comment
Australia		■		Applied throughout Commonwealth and certain states to bills and lower-level rules where costs to business may be high
Austria	■			Recommended for bills
Canada	■	■	■	Regulatory Impact Analysis Statements accompany draft and final regulations summarising any analysis which may be in the form of a Business Impact Test, Regulatory Cost Account Protocol or other equivalent analysis
Denmark			■	Potentially within general impact analysis required for new legal proposals
European Union			■	Required for each proposed regulatory action
Finland	■			Applied to bills and lower-level rules
Hungary			■	Economic evaluation of proposed environmental regulations required
Italy	■			"Cost-output analysis" used
Japan				General impact analysis applied as required
Mexico		■	■	Applied to "business-related" procedures
Netherlands	■			Effects of new regulation on industry/trade
New Zealand	■			Applied to draft laws from Cabinet
Norway		■	■	Economic Impact Assessment of proposed regulations may be CBA; cost-effectiveness of environmental policies
Portugal	■			Applied to certain bills
Spain	■			Assessing the effect of regulatory proposals on public budget
Turkey				General impact analysis for bills
United Kingdom	■		■	Costs of new, amended regulations to business assessed. CBA may be required in specific cases
United States		■	■	Regulatory Flexibility Analyses and CBAs required for actions subject to Executive Order 12866 when not specifically prohibited by enabling statute

Source: Based on data presented in OECD (1997), *Reforming Environmental Regulation in OECD Countries*.

CBA is used in a number of countries, including Australia, Canada, the European Union, Hungary and Mexico, while the US and many European countries such as Denmark, Norway, Germany and the UK (when related to national measures) may require CBA in certain cases (while in other cases its use may be strictly prohibited). In practice, the use of fully quantitative CBA is considered to be the most advanced in Australia, Canada and the US, as these countries more readily apply economic valuation techniques to derive money estimates for changes in risk to the environment and human health.

Under the Treaty of Rome, the European Commission should consider the economic impact of any proposed regulatory options, with the full assessment of the advantages and disadvantages of chemical risk reduction options required where marketing and use restrictions are proposed. However, across and within European Union (EU) Member States, there are differences in the level at which socio-economic analyses are undertaken. For example, some Member States adopt the precautionary principle and call for action, including when the evidence on the existence of risks is disputed, while others adopt a more economics-based approach which insists that actions which could entail large costs should not be taken without a clear benefit (European Commission, 1996). Similarly, there are differing views on the level of assessment which should be undertaken as part of the risk management process. For example, some EU Member States prefer a simple "check box" technique, while others prefer as fully a quantitative analysis as possible.

Within the field of hazardous substances regulation, the US has gone the furthest in preparing fully quantitative CBAs. Assessments carried out within Europe have tended to be at a more semi-quantitative level, as the data and models necessary for full quantification and monetary valuation of the changes in risk to the environment or human health are often not available. These differences stem, in part, from differences in legislation and the degree to which fully quantitative risk assessments are required (with more details of these two systems given in Annex 1). Under the EU system, the output of the risk assessment is in the form of a risk quotient and not of probabilistic information on the risk outcomes. Without the latter information (and supplementary data on the population at risk), it is not possible to place a monetary value on the change in risk.

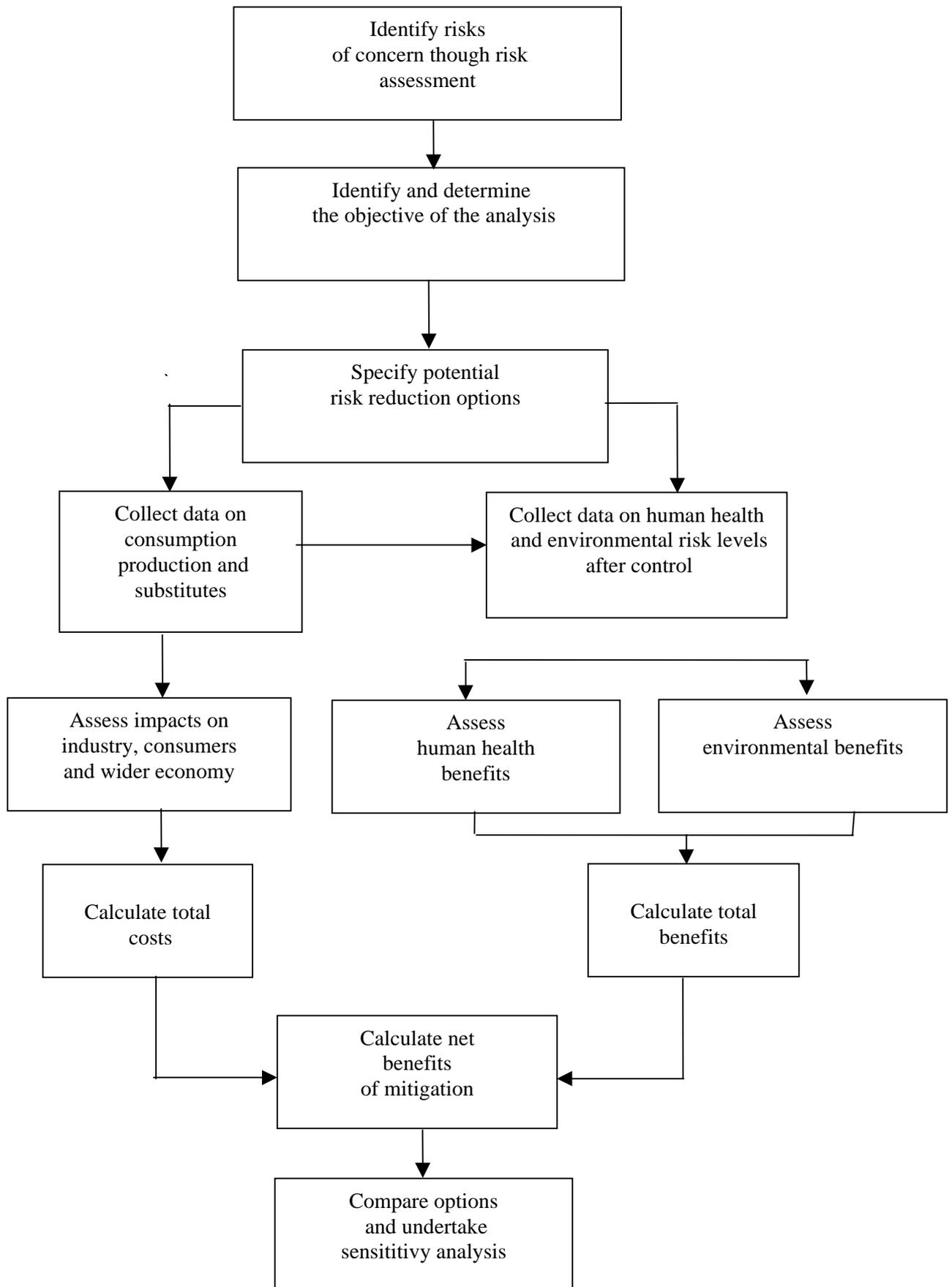
Undertaking a Socio-economic Analysis

Defining the Risk Control Options

Once a decision has been made that, on the basis of the results of a risk assessment, risk reduction is required, the first step is to set out a statement of objective; for example, the objective may be as specific as to reduce the predicted environmental concentration in water from using X chemical in Y application to below Z micrograms per litre. The objectives should be clear from the results of the risk assessment, which should aid decision makers in determining whether the particular use of a chemical presents a potentially unacceptable risk.

Once the objectives have been determined, the next step is to identify what measures could be adopted to achieve the required reduction in risk. Sometimes it is proposed that a total ban is placed on the use of a chemical in a particular application. There are, however, a range of options which may be equally effective at reducing the risks posed by a particular chemical. Options could include, for example, restrictions on particular uses, limits on maximum concentrations, setting limit values for emissions, labelling, voluntary programmes introduced by industry, worker health and safety programmes, recycling/re-use programmes or the provision of information on safe handling and use, and many other types of action.

Figure 1: The Cost-Benefit Analysis Process



Several of these actions could be combined to form an overall control strategy, or risk reduction could depend on just one option. It is likely, though, that the risk, cost and benefit implications associated with different options will vary; in some cases, the variation may be significant. This may be particularly true when regulation is taking place at an international level. In such cases, the risk reduction measure most appropriate for one set of countries may not be appropriate for other countries. This may partly be as a result of existing legal and economic systems, but also because of national differences in levels of exposure and thus the risks faced by target populations.

The Assessment Framework

The balancing of risks, benefits and costs cannot be done in the abstract. It must take into account the specific context of each use of a potentially hazardous substance (or its existence as a chemical contaminant), the particular risks associated with different uses, the benefits and costs arising from use and those associated with the potential alternatives. It is also important that any analysis is systematic and addresses all of the costs and benefits associated with a given risk reduction measure. The analysis must provide adequate information to indicate the need for and consequences of any proposed measure. The aim should be to ensure that risk management decisions are based on the best reasonably obtainable scientific, technical, economic, social and other information.

Figure 1 illustrates the assessment process, which effectively involves the following steps:

- 1) identify the risks of concern and determine the objectives of the assessment;
- 2) specify the risk reduction options to be considered (recognising that additional options may be identified at later stages in the analysis);
- 3) identify the key impacts to be examined (including implications for producers and consumers, human health and the environment);
- 4) collect base data on production and consumption of the chemicals and on potential substitutes;
- 5) determine the stages of (and activities in) production, use and disposal giving rise to potential releases and thus impacts, and assess the change in risks arising from the various risk reduction measures with regard to both the chemical of concern and substitutes;
- 6) estimate the economic implications of different regulatory controls, including private costs and benefits (e.g. changes in producer and consumer surplus) and social (e.g. environmental and health) costs and benefits; and
- 7) evaluate economic versus risk trade-offs associated with the different risk reduction options.

This framework highlights the linkages which should exist between the risk assessment and the CBA stages. The results of a risk assessment should not only help define the objectives of the analysis, but also relate to step (5), which should be based on the procedures established under different regulations, or which are recognised as best practice. The CBA then draws upon this information in order to estimate the implications of the different options. The CBA may also identify other risk reduction options which may provide a more cost-effective means of achieving the end objectives. The process, therefore, should be viewed as an iterative one, with the CBA also informing the definition of new risk (reduction measures).

This type of framework can be applied at two levels, preliminary screening and detailed analysis. For example, it can be used for screening chemicals which are potential candidates for the introduction of risk reduction measures. A preliminary assessment would help identify whether the problem is shared amongst a number of countries, the likely magnitude of costs and benefits associated with taking action, and whether there would be any significant distributional impacts associated with risk reduction. In an international context, this type of assessment may be important to ensuring that attention is focused on those chemicals posing the greatest levels of concern and the control of which would provide the greatest net benefits.

Following on from such a preliminary assessment, a more detailed analysis will be required. In undertaking a fuller analysis, however, it is important that resources are focused on the key elements affecting the decision. Determining what these are will involve a comprehensive examination of available information. For some hazardous substances, a considerable amount of information will exist owing to long-established use or high levels of concern with regard to a particular effect. In other cases, little information is likely to exist, particularly for newer chemicals and/or processes.

Industry and Wider Macroeconomics

In terms of the impacts on industry and consumers, the following categories of potential cost increases (or decreases) may need to be considered within the assessment:

- the costs to industry of adopting substitute chemicals, changing production processes, addressing product effectiveness, and of other required actions which stem directly from the control measure;
- the costs to regulatory authorities of implementing and administering the regulation, where this includes any necessary monitoring and enforcement activities; and
- any macroeconomic costs, where these include effects on prices, changes in productivity, distributional implications, changes in employment and impacts on international competitiveness.

Industry

Risk reduction measures, depending upon their focus, could impact anywhere on the **chain of trade** associated with the use of a substance from raw materials producers, through retailers, to users. It is important, therefore, to identify which links in the chain are likely to be affected and the magnitude of any effects. Given the international nature of the production and use of many chemical-based products, it is likely that the chain of trade may span several countries. The distribution of impacts and their significance may also vary considerably by country.

In determining the costs to producers and others in the chain of trade, a chemical must be viewed as part of a package which provides a service to 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 and may help ensure that double counting is avoided to identify key industries which are as “near” to the consumer of the end-product as possible, and for which the chemical has a clearly identifiable impact. This approach will also help focus data collection and analysis activities so that they are efficient. Where the chemical is used in more than one application, the exercise will need to be carried out separately for each application.

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:

- Chemicals that act as "intermediate products", primarily used in producing other goods, usually will constitute only a small part of the total costs of the final product. As a result, any impacts on the costs to consumers will be small (equivalent to the increase in costs multiplied by the share of those costs in total revenue); while
- In those cases where the costs of the chemical account for a large proportion of end-product costs, the impact on consumers may be significant.

Most hazardous chemicals are likely to fall within the first category, acting as "intermediate products" which are insignificant inputs relative to the overall costs of a product. For example, if banning a chemical led to a 20% increase in the cost of a service, and the cost of that service constituted 5% of end-product costs, then the resultant price increase would be around only 1% and the resultant increase in costs to the consumer would be small. In such cases, the main impact which the CBA would need to consider, therefore, is the increase in costs to the producers. Where a chemical accounts for a large proportion of end-product costs, it will be important to determine changes in costs to consumers. Estimation of these changes will require information on the relationship between changes in price and changes in demand (i.e. the elasticity of demand) and, unfortunately, for many of the end-products likely to be of concern this type of information may not be readily available.

It is likely that a range of different sources will have to be drawn upon to gather the data required for the cost analysis. The data provided by different sources may conflict (e.g. on trends and on the potential of different substitutes and their efficacy), and some industry data may be of a confidential nature. For example, figures on production and intermediate use may be publicly unavailable, and industry may be wary of releasing it, particularly when the affected market segment is highly competitive. Similarly, where a hazardous substance is a minor input to the overall production or 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.

Co-operation from industry is therefore essential, as most cost data are sourced from them. 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 demands on their time may reduce the willingness or ability to co-operate.

Bans on the use of a particular chemical or substance in a given application may be an effective and absolute means of eliminating the unacceptable risks associated with that particular product. However, the introduction of a ban will lead in most cases to the adoption of **substitute chemicals**, whether as direct replacements or as part of the reformulation of a new product aimed at achieving the same end. Such substitute chemicals may not be without their own human health and environmental risks which need to be considered as part of the overall assessment. In determining the risks associated with substitutes, in theory, the assessment should follow the same process as that undertaken for the chemical under investigation. However, for many substitute chemicals, particularly those which have only recently been developed, there will be a paucity of data. Comparative assessments still need to be undertaken in order to address the issue of risk trade-offs, even if only using qualitative information.

The various risk reduction options are also likely to give rise to significantly different implementation costs. Changes in such costs may relate to, for example, licensing an activity, inspection and monitoring, and/or sampling and testing. Consideration should be given not only to cost increases, but also to any savings that may arise. Additionally, potential changes in the administrative costs faced by industry and regulators should be examined.

Human Health and the Environment

One of the key difficulties faced in a CBA will concern how to incorporate and value changes in risk to human health and the environment. To some extent, the manner in which such changes are assessed depends upon the information available from risk assessments:

- Where the output of the assessment is in the form of a risk quotient, insufficient information will be available to place monetary values on any changes in risk; the assessment, therefore, will have to be qualitative or rely on the use of some other form of quantification (i.e. borrowing from multi-attribute approaches)
- Where it is possible to translate the risk quotient to predictions of the frequency of a specified consequence(s), then monetary valuation may be possible.

Essentially, valuation of changes in risk to human health or the environment is based on four sets of data: pollution concentrations (both background levels and mean activity-related levels), dose-response relationships, unit value estimates, and the population or environmental stock at risk. In addition, estimates are required not just for the worst-case scenario, but also for other potential scenarios or outcomes. Economic theory does not argue for decisions based on the expected risks (or benefits or net benefits) but argues, instead, for separating the distribution of risks to the population from estimates of risk aversion. In this case, the risk assessors' use of "worst case" estimates provides only one point in the risk distribution.

Assuming that a full probabilistic risk assessment has been undertaken and that information is available on the population or stock at risk, then valuation may be possible. A number of different economic valuation techniques have been developed to derive monetary values for human health and environmental effects. Those techniques which are most commonly used are as follows, with their relative advantages and disadvantages indicated in Table 3 (also see, for example, OECD, 1995):

- conventional market price or effect on production approaches: these use market prices to value the costs/benefits associated with changes in environmental quality. They include the "dose-response technique", the "cost of illness" approach and the "replacement costs" approach;
- household production function approaches: where expenditure on activities or goods which are substitutes for or complements to an environmental or health related good are used to value changes in the level of the good. Such techniques include the "avertive expenditure" approach and the "travel cost method";
- hedonic pricing methods: these are based on the concept that the price paid for a complementary good implicitly reflects the buyer's willingness to pay for a particular attribute (e.g. contaminant-free food) or willingness to accept an increased risk through, for example, the examination of "wage risk premia"; and
- experimental markets: the two key techniques for this approach are the "contingent valuation method" and the "contingent ranking method", where the public is asked to value non-market goods with a hypothetical market.

Table 3: Valuation Techniques - Advantages and Disadvantages (page 1 of 2)

Technique	Basis of Valuation	Advantages	Disadvantages	Reliability
Dose-Response Technique	Market prices Assesses benefit/gains resulting from action	Straightforward method when markets for goods exist Values may be more acceptable than those derived through other techniques, as based on "hard" data	Problems when cause and effect relationships are uncertain Changes in productivity may lead to changes in supply and price, complication valuation process	Generally good, but fails to capture non-market benefits
Replacement Costs	Potential expenditures to prevent, avoid or compensate for an impact by replacing the service provided Assesses damage costs avoided	Easily applied	Assumes the existing system is optimal Not based on an individual's ability to pay Shadow project requires a standard or sustainability constraint to be valid	Does not value environmental good; cannot be assumed to provide reliable estimates
Avertive Expenditure	Actual expenditure on mitigating environmental effects Assesses damage costs avoided	Easily applied Data may be readily available	Cannot be used when mitigation measure involves secondary benefits Assumes current levels of expenditure are "correct" Does not address question of optimal level of environmental quality	Validity depends upon situation; generally considered to provide a lower bounds estimate

Table 3: Valuation Techniques - Advantages and Disadvantages (page 2 of 2)

Technique	Basis of Valuation	Advantages	Disadvantages	Reliability
Travel Cost Approach	Valuation based on determining costs incurred in visiting a site/undertaking an activity Assesses benefits/gains resulting from action	Extensive application to the valuation of recreation benefits	Large data requirements and potential difficulties in modelling demand function Requires site-specific surveys of visitors Difficulties in dealing with multi-purpose visits	Where data available and modelling concerns addressed, results considered reasonably reliable. Results should be validated against those of other studies Values use related benefit only
Hedonic Pricing Methods	Differences in property values given varying levels of environmental quality Assesses benefits/gains resulting from action	Useful for valuing change in quality between residential areas Relies on use of market data which may be readily available; data may also be less prone to bias than more hypothetical techniques	Individuals must be able to distinguish small changes in quality and understand implications Difficulties in developing model: independent variables, functional form Requires a number of assumptions concerning housing market which may not hold	Only measures values to land-owners. Fails to capture values of other groups or those related to non-use benefits
Contingent Valuation/Ranking Methods	Individuals surveyed to determine willingness-to-pay or willingness-to-accept compensation Assesses benefits/gains resulting from action: or assesses value of damage avoidance	Based on individual preferences Flexible Can be used to derive use and non-use values	Requires surveying of individuals to elicit values Potential biases in results due to nature of questionnaire	When biases are controlled for, should provide reliable estimates Validation can be carried out by comparing results to other studies

Valuing Changes in Human Health

In assessing health and safety benefits, the analysis needs to consider reductions in the risk of fatalities and reductions in the risk of illness, where the latter can be further divided into acute effects and the incidence of chronic disease.

The valuation of a fatality 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. The most common approach is to assume that if individuals will each pay an average of \$X to reduce their probability of death by Y-' per year (where Y-' is very small), then a group of such Y individuals would average one death less per year, and thus would altogether be willing to pay \$XY to avoid one statistical death. \$XY then provides an estimate of the "value of a statistical life" (VOSL). It is important to note that 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, when 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 risk, it is possible to value the benefit of a change in risk which alters each individual's risk by only a small amount.

A review of some of the VOSL values which have been calculated for different OECD countries suggests that the most appropriate estimates of a value of statistical life range between \$3-5 million. These values correspond to a value of \$300-500 for each change in the risk of mortality of 1/10,000 (Marin, 1992). Although such values may seem high, it should be remembered that they derive from estimates of individuals' willingness to pay for very small reductions in risk.

The use of VOSL estimates to value reductions in fatality risks within CBAs concerning management of chemical risks has been questioned on a number of grounds, however. As a result, the adoption of ways of expressing reductions in risks have been recommended, such as the concept of the "value of statistical life-years extended" (VSLY). This approach allows distinctions in risk reduction measures based on their effects on longevity (Graham, 1995), with VSLY representing the impact of premature death on an average individual's life span. Health economists in the US, for example, 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).

Valuation of morbidity effects caused by hazardous chemicals or products can utilise costs such as medical expenses, lost productivity, and losses associated with pain and suffering. These can be valued through the use of "cost of illness" estimates, "avertive expenditure", or through the use of surveys to derive willingness to pay measures.

Valuing Environmental Effects

When valuing environmental costs and benefits, it is important to consider the "total economic value" (TEV) of the environmental assets of environmental assets of concern. TEV is the sum of "use values" plus "passive use" values. Use values (direct, indirect and option) are those associated with the benefits gained from actual use (or "consumption") of the environment and may include private sector uses (industry, agriculture, pollution assimilation and dilution, etc.), recreation activities (fishing, hiking, bird watching, photography, etc.), education and scientific value, and general amenity.

They relate to use both today and in the future (option values). Passive use values (also known in the literature as “non-use values”) are generally considered to represent an individual's willingness to pay to secure benefits for future generations (bequest values), and/or to result from an individual's altruistic desire to preserve an environmental asset and ensure its continued existence into the future (existence values).

Standardisation and Benefit Transfer

Many national governments are adopting standard values for transfer between project and policy evaluation, particularly in the valuation of fatalities and illnesses. Industry also uses standard values within its own decision making; for example, some oil companies assume VOSLs of a few million US dollars and higher when determining emergency response and worker safety requirements.

There is little use of standard values for assessing environmental costs and benefits, however. Although considerable work has been undertaken concerning the feasibility of transferring environmental valuations across different policies and projects (a process known as **benefit transfer**), it is generally argued that this is not yet possible for many impact categories owing to the lack of relevant and robust studies from which to draw.

At an international level, the use of standard values and of **benefit transfer** becomes more controversial. Estimates developed for one country with particular cultural and socio-economic characteristics (e.g. the US) may not be directly transferable to other countries (e.g. EU countries). Cultural perceptions of risks and of environmental quality may be significantly different, and these may invalidate the straight transfer of valuations. In addition, willingness to pay values will depend upon income and the degree of local or national economic development.

Assessing the Trade-offs

Decision makers need documents which present the key findings of a CBA in a clear and precise manner, stating assumptions, data sources and uncertainties contained within the analysis. It is essential, therefore, that both the analysis and any conclusions reached are transparent. Not only will this help ensure that the results are correctly interpreted, but also that users of the results have more confidence in them and are able to see where there are any significant gaps in the analysis which need to be addressed.

Determining the overall pros and cons of different control options will require aggregating the estimates on changes in costs to industry and consumers (producer and consumer surplus) and monetary valuations of impacts on human health and the environment over the time horizon of the analysis. In order to convert the stream of future costs and benefits into a common unit of measure, discounting will be required.

The standard procedure is to calculate the net present value (NPV) associated with a given measure by summing the stream of discounted costs and benefits. In the context of risk reduction, the “costs” are likely to be losses in producer and consumer surplus, while the “benefits” are likely to relate to any environmental and human health gains resulting from control. A positive NPV indicates that the environmental and health benefits outweigh the private costs and that the control measure is justified in economic efficiency terms. If the NPV is negative, the control measure would not be justified in

economic terms. Overall, the measure considered to have the highest NPV is that which is preferred over the others.

It is unlikely, though, that all environmental and health effects can be captured in the socio-economic analysis, and it will be important that the non-monetised risks are balanced against the estimated monetary costs and benefits in the final assessment. In order to ensure that a balance is achieved, it will be important for the final analysis to highlight the implications of risk reduction and the trade-offs involved in selecting one risk reduction option over another. Care must be taken to ensure that non-quantified effects are not automatically given less weight than those which have been quantified and valued. The use of ranking techniques, matrices, checklists and other similar devices can help provide an overview of costs and benefits and thus highlight the differences between control options.

In addition, the distributional implications of risk control should be considered, where this refers to the manner in which the costs and benefits fall across different population groups and/or industrial sectors. Costs and benefits may be distributed evenly across society, or costs may fall upon one small group and the benefits on another. Similarly, costs and benefits may occur unevenly over time, perhaps spanning several generations.

Predictions of the impacts of alternative policy options will be characterised by uncertainty and the importance of this should be recognised. These uncertainties need to be made explicit and an indication given of their significance. Assessments should clearly state the origins of key data, the nature of any models used for predicting effects, key assumptions and when and how expert judgement was used. Justification should be given for the choices made, and an indication should be provided of the effects of these choices on the analysis. At a simple level, the use of scenario analysis and sensitivity testing can be used for handling uncertainty within CBA. More sophisticated approaches include the development of statistical probability distributions for key uncertain variables.

The Development of International Guidelines

The Needs of Decision Makers

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 should be. This in turn requires answers to the following questions:

- What are the risks?
- Do the risks need to be reduced? (or, may it be desirable to reduce 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 option?

The first of these is answered through risk assessment and the second by reference to risk criteria, while the remaining questions are addressed through the use of socio-economic analysis. Risk management describes the overall process by which answers to these questions are found and also includes the means for identifying chemicals for assessment and putting the mechanisms in place for controlling risks, developing risk communication strategies, and monitoring and enforcement.

Risk management has played a vital role in reducing the risks to man and the environment from chemical usage over the last few decades. Action has been taken to control those risks which were clearly unacceptable and to reduce risks in those cases where the costs of so doing were minimal. The risks which remain may be difficult to eliminate without also foregoing the benefits provided by the associated products. The quest, therefore, is to achieve a balanced view concerning which risks are acceptable and which are unacceptable. Achieving this balance will be increasingly complex as obtaining risk reductions becomes more difficult and expensive and the scope of control widens to include consideration of a broader range of effects.

Implications for International Assessment Guidelines

The previous sections have presented the key principles and issues involved in the preparation of a CBA. In particular, a framework for undertaking such analyses was detailed, whether this involved a qualitative, semi-quantitative, or full monetary CBA. The approaches for assessing changes in costs and benefits were outlined, together with a discussion on the presentation of analysis results.

On the basis of the above, a series of recommendations concerning the issues which should be considered in the development of a set of internationally agreed guidelines on CBA are made below. The aim of these recommendations is not to provide rigid and prescriptive requirements but to suggest a pragmatic approach which will be flexible enough for adoption by a wide range of legislative systems, while also providing analyses which are robust enough to provide decision makers with the confidence they require.

The issues which should be considered are as follows.

- 1) **Product- or Process-based Decisions:** 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 of not only the risks associated with those uses, but also 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 regulation of the chemicals associated with the problem (as distinct from taking the chemical as the starting point). A preliminary screening application of CBA may also help in informing the process of selecting which health or environmental issues should be given priority.

- 2) **Estimating and Characterising the Risks:** Usually this will be via a risk assessment, conducted either as part of the study or prior to it. An integrated assessment can use other sources to establish the risks of the substance in question and can include the use of product safety data sheets, previous studies or established data sources. Where possible, the risk assessment should go beyond the calculation of hazard quotients to the full probabilistic prediction of potential outcomes. This will help to achieve more fully quantitative CBAs. It is also important that the estimation of risks is transparent to allow the necessary feedback between the CBA and the identification of alternative risk reduction measures; this is particularly important in an international context, as is the need for commonly agreed assessments.
- 3) **Understanding the Product/Process:** Once a chemical has been identified as posing a potentially unacceptable risk, it is vital that the manner in which a chemical or product is used is understood. This should include determining the chain of trade and the relative impacts at each stage in the chain, and 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. Not only will this aid in the identification of the areas of industry 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 substitute chemicals or products. This assessment should be international in scope and should link into consultation activities.
- 4) **Identifying Risk Reduction Measures:** The above information can also be invaluable in defining an imaginative set of risk reduction measures, rather than relying solely on those measures which relate to a whole or partial ban on the use of the substance. Such alternative measures may confer the same level of risk reduction, but at significantly lower costs to both industry and society more generally. As indicated above, the development and assessment of risk reduction measures should be iterative and feed back into the risk assessment.
- 5) **Identifying the Areas of Impact:** Different risk reduction measures are likely to have different impacts, and care should be taken to ensure that the full range of potential costs and benefits are considered. Impacts to be considered should include the changes in health effects and environmental quality, impacts on the levels of production, changes in product prices, changes in levels of employment, and so on.
- 6) **Consultation with Those Impacted:** Consultation will probably be central to the development of quantitative estimates of impact. Consultation allows those involved in production, consumption, or other aspects of use to provide data concerning the effects on them of controls on the product/process under question. One of the most vital groups in this regard is likely to be trade associations, as they may be able to provide a single set of data quickly from many related sources, saving potentially limited time.
- 7) **Assessing the Implications of Chemical/Product Substitutes:** Many risk control measures rely on substitute products or chemicals being available for adoption by industry. In some cases, such substitutes may not be readily available, while in others there may be process and quality penalties

associated with their use. Analyses should, therefore, examine the implications of adopting substitute chemicals, where this includes asking questions concerning the level of risk posed by the chemicals/products. Care should be taken to ensure that biases are not introduced into the findings towards new chemicals, for which the data on risks are likely to be unavailable or the performance of which is unproven. It must be remembered that a move to substitutes is not necessarily a “good thing”, as they may pose greater risks (or just shift the risks to a different group of receptors) than the product/process under analysis. At this stage, it may be important to ensure that there is a feedback loop between the CBA and the risk assessment. The analysis may generate new ideas on control measures which would be cost-effective and it may be important to be able to determine the changes in risk that such measures would yield. The need to assess the implications of substitutes, however, should not lead to undue delays in decision making.

- 8) **Quantifying the Impact of Proposed Control Measures:** Once those impacted are identified and data have been collected, quantification allows the analyst to compare proposed controls on an equal basis. The greater the level of quantification achieved, the more robust the end results are likely to be. Quantification also helps ensure that important health and environmental issues are given equal consideration to the more traditionally valued impacts on industry and consumers. The level of sophistication of the analysis, however, should be commensurate with the implications of the decisions to be made. The added time and resource costs associated with monetary valuation of all impacts, and in particular human health effects and changes in environmental quality, should be weighed against the added assurance of more informed decision making.
- 9) **Establishing Standard Values:** The use of standard assumptions concerning key variables such as discount rates, time horizon for the analysis, and value of an extended life year or of a statistical life can help in ensuring that there is consistency in analyses and hence in regulatory policies. This may be particularly important where risk reduction proposals are international in scope.
- 10) **Establishing the Trade-offs:** The trade-offs associated with the adoption of a risk reduction measure (or the choice of one risk reduction option over another) will need to be clearly presented and described. Where quantification and valuation have 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 valued in monetary terms.
- 11) **Making Recommendations:** The results of the analysis may lead to a range of different types of recommendations. It is important that at this point in the analysis consideration is given to factors such as the need for derogations, further data collection, etc.
- 12) **Reporting Procedures:** Presentation of the findings in a clear and transparent manner is central to ensuring that decision makers and those affected by the decision understand the results and are able to feed them into the decision making process. This can also help in building a shared commitment to the effective implementation of risk reduction measures.

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Thus, it may be important for procedures to be set 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.

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Annex 1:

Management of Hazardous Chemicals in the US and EU

Risk Management for Toxic Substances in the US

Process of Risk Management

In the US, several different agencies have responsibility for managing the risks associated with dangerous substances. Despite this divided and sometimes overlapping jurisdiction, the Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) has the broadest authority and program to address the risks of both existing and new chemicals. The risk management framework involves the following steps (Axelrad, 1993):

1. identification of chemicals for regulatory control
2. use and substitutes analysis
3. risk assessment
4. economic assessment
5. risk of substitutes analysis
6. regulatory impact analysis

Since the early 1980s, economic assessment has played a role in decision making concerning the control of substances in the US. Under Section 6 of the Toxic Substances Control Act (TSCA), the EPA is required to balance the risks and benefits of the use of a substance with the costs of regulatory control (Axelrad, 1993). Some consider that CBAs are implicitly required under Section 6 of TSCA and that steps two, four and six of the risk management process can be viewed as separate stages of CBA (DoE, 1995a).

Executive Order 12866, as well as a working paper released in 1996 by the Office of Management and Budget (OMB) titled *Economic Analysis of Federal Regulations Under Executive Order 12866*, establish a regulatory philosophy for risk management which is spelled out in its Principles of Regulation. These principles require that:

- in setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of risks posed by substances or activities within its jurisdiction;
- regulation should be in the most cost-effective manner to achieve the regulatory objective; both the costs and benefits of the intended regulation should be assessed and, recognising that some of these are difficult to

quantify, a regulation should be proposed or adopted only upon a reasoned determination that the benefits of the intended regulation justify its costs; and

- each agency tailors 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 cost of cumulative regulations.

Chemicals for regulatory control are identified by the OPPT through a two-stage process. During the first stage (known as RMI), existing chemicals are reviewed and recommendations are made for further action. Chemicals for which there are "potentially significant concerns" find their way onto the Risk Reduction List and are subject to a more detailed review (Axelrad, 1993). The aim of this second stage assessment (known as PM2) is to examine the risks posed by the chemical throughout its life cycle in order to identify opportunities for risk reduction.

When the need for regulatory control is identified, then a "use and substitutes" analysis is undertaken. This collates 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. As such, the use and substitutes report forms the main input to the economic analysis. The risk assessment summarises the risks to human health and the environment associated with the chemical and highlights any associated uncertainties.

Economic Assessment and Risk of Substitutes Analysis

The aim of the economic assessment is to identify different regulatory and non-regulatory options and to develop estimates of their costs and benefits. One of the key requirements of the analysis is that it is transparent, with a thorough explanation of methodology and key assumptions as well as clear presentation of 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 the use of such substitutes results in reductions in risk. As such, this forms a key input into the decision making process. Based on the results of the above assessments, a decision is made as to the preferred option.

Risk Management for Toxic Substances in the European Union

The Legislative Framework

Legislation in the European Union requires that, when chemicals and other dangerous products are marketed in the Community, the associated risks should be assessed and where appropriate reduced. The legislative framework is provided by the directive for dangerous substances and preparations (67/548/EEC) and associated implementing directives and regulations (with the key ones being Directive 93/67/EEC, Regulation (EEC) No. 793/93 and Regulation (EC) No. 1488/94). The Directive was originally conceived as a means of harmonising specifications which could otherwise create obstacles to the free movement of goods throughout the community. However, subsequent amendments were aimed at ensuring chemical safety and environmental

protection. The other directive of direct relevance to risk management is Directive 76/769/EEC on the marketing and use of dangerous substances and preparations. It is under this directive that bans and other controls can be placed on dangerous substances.

The requirements of Directive 67/548/EEC (and 76/769/EEC) apply to all dangerous substances and preparations except those which are covered by product-specific directives which incorporate the necessary requirements. For example, pesticides are covered by a series of pesticide directives including 91/414/EEC and 79/117/EEC.

The Risk Management Framework

In a Draft Working Paper on Risk Management (European Commission, 1996), the European Commission defines risk management 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." The legislative framework discussed above implies the following approach to risk management:

- identification of chemicals for consideration;
- risk assessment;
- risk evaluation; and
- risk mitigation or control.

Identification of Chemicals for Risk Management

Under Directive 93/67/EEC, before a new dangerous substance can be placed on the European market, an assessment of the associated risks must be undertaken. With respect to existing substances, risk assessments are prioritised under Regulation (EEC) No. 793/93, which makes provision for setting up priority lists of existing substances in order to target risk assessment at key chemicals of concern. In addition to these, "programmed assessments" and "ad-hoc assessments" are undertaken when required, for example (European Commission, 1996):

- when new evidence suggests that the risks associated with a substance may have been underestimated;
- when Member States notify the Commission that they wish to introduce regulations for chemicals which are not on the priority list; and
- when controls are proposed by bodies outside the European Union such as the Paris Commission (PARCOM - the EU is a Party to PARCOM and is required to implement PARCOM's decisions restricting the use of chemicals).

Risk Assessment and Evaluation

Directive 93/67/EEC lays down common principles for assessing and evaluating the risks to human health and the environment which are posed by new substances, while Regulation (EC) No. 1488/94 is for 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 for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances* and are undertaken by Member State Governments on behalf of the Commission according to the following four steps:

- hazard identification;
- dose-response assessment;
- exposure assessment; and
- characterisation or risk.

The final step of the risk assessment (i.e. risk characterisation) is the main means by which risks are evaluated. Risks are characterised by comparing effects with exposure and recommendations are made concerning the need for risk reduction or mitigation. For example, with respect to the environment, the need for further action is determined from the risk quotients for water, air and soil. When:

- $PEC/PNEC < 1$, the risk is acceptable; and when
- $PEC/PNEC > 1$, the risk is not acceptable and action is required.

The assessment is designed to derive the risks associated with the “reasonable worst-case” scenario, the aim being to ensure that risks are not under-estimated. To enable risks to be assessed in the absence of data, the guidelines provide default assumptions. These, which are used in conjunction with the detailed risk assessment methodology set out in the guidelines, seek to ensure that risks are consistently assessed across all European Member States.

Risk Mitigation or Control

Draft Guidance prepared by the UK Government for the European Commission on the development of risk reduction strategies puts forward the following five-step approach to risk mitigation or control (Department of the Environment, 1995b):

- **Step 1:** Identify which specific stages in the manufacture, storage, distribution, use or disposal of the substance have been highlighted by the risk assessment as giving rise to risks which need to be limited.
- **Step 2:** Taking account of any existing risk reduction measures, 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, draw up analysis of advantages and drawbacks and of availability of alternatives.

Risk reduction measures can take the form of voluntary agreements or regulatory controls at both the EU and Member State level. Regulatory controls can be directed at legislation on (Department of the Environment, 1995b): marketing and use; pollution control; distribution and storage; waste management; classification and labelling; and worker protection.

EU Technical Guidance Document on Development of Risk Reduction Strategies

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Introduction

The European Community adopted Regulation 793/93 on the evaluation and control of the risks of existing chemicals on 23 March 1993. This has initiated a major programme to collect basic information on high tonnage chemical substances, and to evaluate and where necessary control the risks of selected priority substances to human health and the environment.

The process of assessing a priority chemical under the Existing Substances Regulation is illustrated in Figure 1. Member States ("rapporteurs") are assigned a number of individual priority substances to evaluate. Where appropriate, rapporteurs must suggest a strategy for limiting the risks arising from the substances. Both the risk assessment and any risk reduction strategy will be submitted to the Commission. The Commission will then submit a proposal concerning the results of the risk evaluation, and, if necessary, a recommendation for an appropriate strategy for limiting those risks to the Committee of Member States' representatives. The results of the risk evaluation of the priority substances and the recommended strategy will be adopted at Community level in accordance with the procedure laid down in the Regulation and will be published by the Commission. The Commission will then decide, where necessary, to propose Community measures within the framework of relevant existing Community legislation.

The EU Technical Guidance Document on Development of Risk Reduction Strategies provides guidance for the rapporteurs when choosing the recommended strategy. It covers that part of the process from the identification of any risks which need to be limited through risk assessment to the rapporteur's submission of the risk assessment and any accompanying risk reduction strategy to the Commission. The guidance is not legally binding, but represents a common commitment by the Commission, Member States and participating non-governmental organisations on how risk reduction recommendations pursuant to Regulation 793/93 should be framed.

The rapporteur should develop a risk reduction strategy tailored to the circumstances of the individual chemical. Rapporteurs should consult industry and others, so that the strategy is developed through an interactive process making use of all the main sources of information on the substance and possible control measures. To help the rapporteur in this task, much of the document is concerned with describing the wide range of risk reduction options available, and with guiding the rapporteur on the factors to take into account when selecting the most appropriate strategy.

The process of developing the strategy is described in six steps, as presented in Figure 2, and this paper briefly outlines the main features of each step.

Figure 1. The Process of Assessing a Priority Chemical and Developing a Risk Reduction Strategy under the Existing Substances Regulation (EEC No. 793/93)

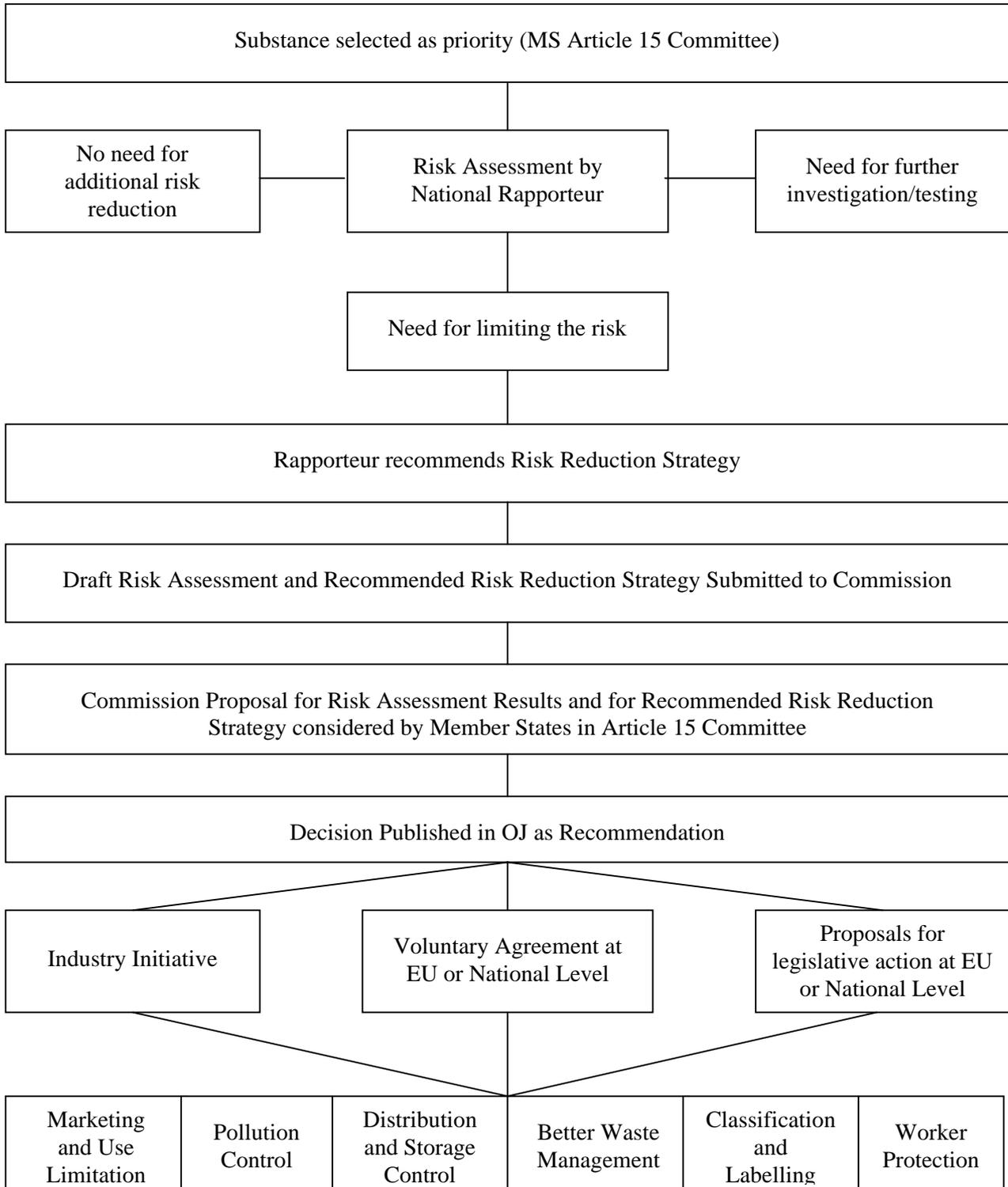


Figure 2. Developing a Risk Reduction Strategy

- Step 1* **Identify which specific stages in the manufacture, storage, distribution, use or disposal of the substance have been highlighted by the risk assessment as giving rise to risks which need to be limited**
- Step 2* **Taking account of any existing risk reduction measures, 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, draw up an analysis of the advantages and drawbacks and of the availability of alternatives**
- Step 6* **Submit the risk assessment and any recommended risk reduction strategy in the correct format to the Commission**

Assessing potential risks

Step 1

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

The basis for drawing up a risk reduction strategy is the risk assessment. Indeed, it is only when the risk assessment concludes that there is a risk that needs to be limited that the rapporteur should develop a risk reduction strategy. The risk assessment will identify the magnitude and character of the risks foreseen for a substance. The risk assessment will identify not only the risks which need to be limited: it will also identify where such risks arise, and which exposure routes the risk reduction strategy will need to address.

Commission Regulation (EEC) No 1488/94 lays down how risk assessments must be carried out. This has been supplemented by detailed technical guidance documents, and the process is not examined further here.

Risk reduction measures

Step 2

Taking account of any existing risk reduction measures, identify the options available for effectively reducing the risks which need to be limited

The guidance document provides an inventory of potential risk reduction measures. A wide range of risk reduction measures are available, allowing the rapporteur to develop a strategy suited to the circumstances of each individual substance. Measures fall into a limited number of generic categories: for example, information requirements; restrictions on marketing and use; and controls on emissions.

This section of the guidance gives examples of risk reduction measures that may be appropriate at each of the stages of a substance's life cycle. It also provides some general criteria as to assessing the effectiveness of the measures in different exposure situations.

Implementing risk reduction measures

Step 3

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

This section of the guidance lists the range of policy instruments, including, for example, voluntary approaches, economic instruments and regulation, which can be used in the implementation of the risk reduction options identified above. These instruments are not mutually exclusive, and a combination of different instruments may often be the most effective approach: for example, a voluntary agreement may need to be underpinned by regulation.

The guidance outlines the strengths and weaknesses of main policy instruments, including:

- information programmes and other EC/government initiatives
- unilateral action by industry
- voluntary agreements
- technical standards and authoritative guidance
- economic instruments
- regulatory controls

Recommending the most appropriate approach

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

In selecting the most appropriate risk reduction strategy, the rapporteur should:

- identify the range of possible options from the inventories of risk reduction measures and methods of implementation provided in earlier sections; and
- assess this range of options to identify the most appropriate approach taking into account criteria such as effectiveness; practicality; economic impact; and monitorability.

This section of the guidance provides guidance on both stages of this process.

When identifying the possible options, the rapporteurs are advised to pay attention to, e.g.:

- how to effectively reduce the risks while imposing the minimum necessary burdens on society as a whole;
- whether the action should be taken at Community level or at the level of individual Member State(s);
- the imminence and degree of any risks identified and to a possible need for quick implementation; and
- whether precautionary action is necessary.

In choosing the most appropriate approach, the rapporteurs are recommended to evaluate the options considering the following criteria:

- 1) **Effectiveness.** The measure (or measures) must be targeted at those significant hazardous effects and routes of exposure where risks that need to be limited have been identified by the risk assessment and must be capable of reducing the risks that need to be limited within and over a reasonable period of time;
- 2) **Practicality.** The measure (or measures) should be implementable, enforceable and as simple as possible to manage [such that smaller enterprises are able to comply]. Priority should therefore be given to consideration of commonly used measures that could be properly carried out within existing infrastructure (though not to the exclusion of novel measures);
- 3) **Economic impact.** The rapporteur can make a rough qualitative estimate of the impact of the measure on producers, processors, users and other parties on the basis of his experience and judgement. However, regarding restrictions on marketing and use the rapporteur should provide a more detailed analysis of the advantages and drawbacks of the measures;
- 4) **Monitorability.** Monitoring possibilities should be available to allow the success of the risk reduction to be assessed.

Analysing advantages and drawbacks if marketing and use restrictions are under consideration

Step 5

If marketing and use restrictions are recommended, draw up an analysis of the advantages and drawbacks and of the availability of alternatives

Basic principles

If the rapporteur concluded that the most appropriate approach to risk reduction is the restriction of marketing and use of the substance, the Existing Substances Regulation requires the rapporteur to submit an analysis of advantages and drawbacks of the substance and of the availability of replacement substances.

Since any legislative implementation of the proposed restriction will not take place under Regulation 793/93, but normally under Directive 76/769/EEC (limitations on marketing and use), the appraisal of advantages and drawbacks is of pre-analytical nature. This means that, if necessary, the appraisal carried out under the Existing Substances Regulation will be supplemented later, i.e. when the actual implementation is discussed.

The Existing Substances Regulation requires the rapporteur, if marketing and use restriction is recommended, to "submit an analysis of the advantages and drawbacks of the substance and of the availability of replacement substances". However, in the guidance this provision is deliberately recommended to be broadened to cover the advantages and drawbacks of adopting the recommended restrictions on marketing and use. Consequently, the appraisal would then not only cover the risk reduction of the substance, but also the possible adverse effects of the substitutes ("net advantages or net benefits"). Similarly, not only the advantages of the substance as currently used should be addressed, but also the positive and negative consequences to industry

and society in general that may be caused by the restriction, such as loss or increase of market and jobs ("net drawbacks or net costs").

Framework

The guidance does not require any particular approach or methodology that should be used in the appraisal. The rapporteur can choose the approach that best suits the specific circumstances of the substance in concern. However, some major outlines are described in the following in order to help the rapporteur in planning and performing the analysis, and other partners in reviewing it.

The analysis of advantages and drawbacks can be divided into the following phases, which are discussed in detail in the guidance

- choice of alternative control measures,
- choice of decision criteria,
- collection and presentation of data,
- comparison of advantages and drawbacks,
- drawing the conclusions, and
- dealing with uncertainty.

These steps can be taken iteratively, with the aim being to find a sound basis for decision making with optimal use of resources.

Usually, it is appropriate to start with a qualitative analysis, and to move to semi- or fully quantified analysis, if necessary and possible. A qualitative analysis can be regarded as a minimum requirement for the rapporteurs. The extent of the analysis shall be decided case by case, on the basis of, for example

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

Rapporteurs are recommended to consult widely amongst relevant parties during their appraisal and to ensure a close co-operation between risk assessors and risk managers. This will be of special importance if monetarisation or other quantification of the risks is under consideration.

The alternative control measures (decision options) in the appraisal may be, e.g.

- restriction on marketing and use vs. the current situation,
- partial vs. full restriction, and
- restriction vs. some other type of control measure (e.g. emission control).

The impacts or consequences of the decision that are considered in the appraisal and that finally affect the decision are called decision criteria. In a broad sense, the decision criteria in this context are advantages and drawbacks, but it is practical to have a more detailed description of criteria that should be considered. The criteria may vary from case to case, but in this context they could usually fall into the following categories:

- 1) risks of the substance to human health and the environment,
- 2) risks of the substitute(s) to human health and the environment,
- 3) costs and benefits to the producer of the substance,
- 4) costs and benefits to the producer of the substitute,
- 5) costs and benefits to the user or other stakeholders, and
- 6) other factors, such as administrative burden, employment, etc.

Data collection and presentation

For the analysis of advantages and drawbacks, the risk assessment of the substance of concern is a vital source of information. In addition, further data need to be collected concerning

- 1) the alternative substances (both in relation to technical/economic feasibility and possible hazard/risk posed by the substitutes), and
- 2) economic impact and socio-economic consequences.

For alternative substances, the rapporteur should try to characterise to what extent the risk posed by the substance will be reduced, taking into account the possible new risks caused by the substituting chemicals or alternative techniques. In practice, this is a demanding task, and due attention must be paid to how far the rapporteur should proceed with the assessment of substitutes. The guidance is flexible and a stepwise approach is recommended, in order to move no further than necessary for the demonstration of the likely risks of the alternative substances. In all cases, the available information of the hazard profile of the substitutes should be assessed and described. To what extent the exposure to (and consequently the risks of) the substitutes should be evaluated is a matter of case-by-case judgement. The upper limit of substitute evaluation is the prioritisation under Regulation 793/93, but since it is both time-consuming and resource-intensive, it should only be done after careful consideration and consultations.

The technical and economic aspects of the substitutes also need to be addressed in order to define their performance and economic feasibility. It can be useful to carry out a rough ranking on the basis of these aspects, in order to restrict the number of substitutes that should be studied more closely.

When evaluating the substitutes, it is recommended to take into account the dynamic nature of the situation; technical progress and development of the market can be rapid. For example, it is useful to consider whether the substitution in some Member States has already taken place, and what experience is available in that case.

The goal of appraising the economic impact is to identify the extent and distribution of the economic consequences the restriction is likely to have. In this context the economic impacts are understood to cover both the direct impacts to industry and consumers involved and their indirect consequences, such as effects on the

employment. The data used for the appraisal can be both qualitative and quantitative. It may be enough to start with a qualitative or only partly quantified data, and further quantification will be performed only if necessary.

The economic impact of the restriction can be evaluated coarsely by identifying the direction and the extent of the impact, and the type of the additional costs or savings (e.g. investment, operating cost, maintenance).

The guidance also provides a detailed list of questions which may be helpful in a more thorough appraisal of economic consequences.

The rapporteur should try to present and summarise the data as clearly as possible. The data sources, estimation techniques, assumptions and extrapolations should be presented for the sake of transparency.

One possibility for summarising the data is to use a matrix, which includes a cross-tabulation of alternative control measures and decision criteria. This type of matrix can be used to structure and to summarise the data that have been collected and the evaluations performed. The decision matrix should always be accompanied with an explanation of how the data were derived and processed, and what uncertainty is involved. Figure 3 gives an example of a possible matrix.

Figure 3. Example of an evaluation matrix

CRITERIA	ALTERNATIVE CONTROL MEASURES		
	Current situation	OPTION 1	OPTION 2
Environmental risk of the substance			
Environmental risk of the substitute			
Health risk of the substance			
Health risk of the substitute			
Cost or benefit to the producer			
Cost or benefit to the user			
Cost or benefit to the producer of the substitute			
Other factors (administrative burden, employment, etc.)			

Comparison of advantages and drawbacks

Qualitative analysis

Once the data collection has been completed and the data are described and summarised appropriately, a first attempt can be made to compare the balance of advantages and drawbacks. A qualitative assessment means that

- the data are presented in a qualitative manner, although some of the data may well be expressed in quantified form;
- the comparison of advantages and drawbacks is carried out to determine if the advantages outweigh the drawbacks, or vice versa.

It might be possible to draw firm conclusions from the analysis if, for example,

- some of the alternative control measures lead to clearly unacceptable consequences (e.g. immediate severe environmental or human health damage is likely to occur, the likely economic impacts are too severe); or
- it is possible to define an acceptable order of preference for the criteria; then the alternative with the best value in the most important criteria will be chosen (e.g. if one must choose the most effective alternative in terms of risk reduction).

Qualitative data usually contain a considerable amount of uncertainty, and it might be difficult to comprehend their practical importance and to compare the different criteria to each other. Therefore, it may be difficult to assess the balance of advantages and drawbacks purely on a qualitative basis.

Quantitative analysis

Quantification of data can be used to make the different impacts more understandable, to simplify the comparison of advantages and drawbacks, and to reduce the uncertainty. Quantification means the assignment of a quantitative (numerical) value (or a set of values, or a distribution) for a certain impact. Quantification can be partial (semi-quantitative), or cover the whole data (full quantification). In a semi-quantitative assessment usually only some of the decision criteria, such as part of the economic impacts, are quantified.

Although quantification can help decision making, quantified information should not be automatically given a greater weight in relation to impacts described qualitatively. Furthermore, quantification usually implies additional assumptions which can also give rise to additional uncertainties.

Also, quantified data can be expressed in different ways. A distinction can be made between physical units and commensurate units. Physical units (also sometimes called "natural units") describing the risk can be, for example, the PEC/PNEC ratio, the margin of safety, the excess probability of an adverse effect, or numerical values describing the extent of the exposure (such as amount of emission or number of exposed workers).

When using physical units, the rapporteur still faces the problem of valuation, which makes the comparison of advantages and drawbacks complex. Valuation techniques have been developed to overcome this problem, which makes it possible to express different impacts in uniform and commensurate units. The most usual commensurate unit is the monetary value, but it is also possible to create commensurate units using

different scoring techniques. This enables the direct trade-off between, for example, economic aspects and risks to human health and the environment. However, these techniques are still being discussed controversially.

Monetarisisation is an essential part of cost-benefit analysis. Monetarisisation of human health risks can be used to give a money value for avoided costs (like reduction in medical costs or loss of working days due to illness) or for so-called statistical life. Likewise, the environmental impacts can be quantified to describe, for example, the loss of use value of nature resources (like fishery, clean air or water), or the reduction in costs caused by pollution (remediation costs). In principle, it is easier to assess the (objective) use values or avoided costs than the (subjective) non-use values.

There are, however, several limitations in the applicability of valuation techniques in the context of the Existing Substances Regulation. The outcome of the risk assessment is expressed as a ratio of exposure level and no-effect level together with other factors, whereas a fully quantified risk estimation would require that the outcome is presented as a probability of a certain effect with the current exposure. The risk assessment is a so-called generic assessment, which is not directly connected to specific time or place. This makes it rather difficult to communicate the risk in concrete and understandable terms, which is usually the condition for using monetarisisation techniques. This, however, should not lead to the conclusion that the risk assessment should be further amended.

Dealing with the uncertainty

In all available information for the analysis of advantages and drawbacks a certain amount of uncertainty is incorporated. In principle, this uncertainty should be acknowledged when comparisons of alternative control actions as well as of advantages and drawbacks are made.

The guidance recommends the rapporteur to use some simple procedures based mainly on expert judgement to characterise the level of uncertainty. For example, by

- using ranges rather than point estimates,
- using threshold values, or
- performing a coarse sensitivity analysis.

Drawing up a formal risk reduction strategy for submission to the Commission

Step 6

Submit the risk assessment and any recommended risk reduction strategy in the correct format to the Commission

Having identified the risk reduction measure or measures that will most effectively reduce the risks which need to be limited while imposing the minimum necessary burden on society, the rapporteur will be in a position to draw up a risk reduction strategy for submission to the Commission. The level of detail of any recommendations for further action will in part depend on the complexity of the problem and the information available to the rapporteur. However, while the rapporteur is encouraged to analyse the available data, the action suggested will usually be of a generic nature.

The guidance suggests a common format for the submission of risk reduction strategies to the Commission.

The Commission shall, on the basis of the rapporteur's draft risk assessment and risk reduction strategy and further to bilateral discussions with other interested parties, then prepare a proposal to the Article 15 Committee under the Regulation, which will subsequently be the subject of formal proposals under other pieces of Community legislation.

Summary: Developing a risk reduction strategy

The process of developing a risk reduction strategy for a priority substance can be briefly outlined as follows:

- 1) Summarize any risks identified by the risk assessment as needing to be limited, the magnitude of these risks and the particular activities that give rise to concern;
- 2) Consult industry, Member States and other interested parties informally;
- 3) Consider whether risks could be effectively reduced by increasing the effectiveness of existing controls;
- 4) List further measures with the potential to effectively limit the risks in question;
- 5) Identify the most appropriate tools for implementing these potential risk reduction measures;
- 6) Identify the most appropriate risk reduction measure or measures by evaluating the list of potentially effective risk reduction measures and means of implementation against the following criteria: effectiveness; practicality; economic impact; and monitorability;
- 7) Consider whether the selected measures will effectively limit the risks without significantly increasing risks elsewhere or otherwise imposing disproportionate burdens on society;
- 8) If controls on marketing and use are envisaged, draw up analysis of the advantages and drawbacks of the substance and of the availability of appropriate replacement substances;
- 9) Outline any uncertainties in the information and methodologies on which the strategy is based;
- 10) Where appropriate, draw up recommendations for monitoring effectiveness of strategy;
- 11) Describe how the recommended strategy offers a significant net risk reduction;
- 12) Consult those with relevant technical and economic expertise, industry, Member States and other interested parties as appropriate;
- 13) Submit the recommended strategy to the Commission;
- 14) In light of technological breakthroughs, or of new knowledge on potential risks to human health or the environment which significantly changes the risk assessment, a new strategy should be considered.

Cost-Efficiency Studies: A Tool to Examine the Most Effective Way to Realise Necessary Risk Reduction Measures

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Summary

The aim to protect man and the environment from the hazards resulting from production, use and disposal of chemical substances is achieved by comparing concentrations in environmental compartments (PEC) with concentrations at which no effects on organisms or ecological systems are expected to occur (PNEC). If the PEC in an environmental compartment exceeds the respective PNEC, risk reduction measures are necessary. When restrictions on marketing and use are proposed, the Existing Chemicals Regulation of the EU demands an analysis of advantages and drawbacks of risk reduction measures, in which possible substitution products are to be taken into account.

Such an analysis should generally not question the results of a risk assessment. Rather, there should be a consensus that a risk established using the methods prescribed in the Technical Guidance Documents of the EU on Risk Assessment must entail suitable measures or, in other words: that the issue at hand is not the “whether“, but the “how“. Monetizing the damage or risk avoided if no reduction measure is performed is not absolutely necessary in this context. Instead, the most cost-efficient risk reduction measures should be selected on the basis of cost-efficiency considerations.

It should be kept in mind that the possibility of undertaking quantitative cost-benefit analyses is reduced by a lack of available data. In many cases, considerable cost is likely to be incurred in generating the necessary information, with the consequence that necessary decisions on risk reduction measures might be postponed. Due to the high proportion of intangible costs and benefits as well as the inherent need for preliminary political decisions, the results obtained in such analyses must be interpreted with caution. These limitations reduce the value of a cost-benefit analysis and can give rise to a number of manipulations. Similar problems arise when a comparison with possible substitution products has to be performed, in which usually even less information is available. Here, the positive aspects of a conversion to alternative substances or technologies should by no means be underestimated.

Due to the complexity of the subject, the EU Technical Guidance Documents for Risk Reduction suggest a stepwise approach, starting with qualitative analyses and extending it to quantitative ones only when necessary.

Examples/case studies for cost-efficiency studies will be presented.

Introduction

Similar to what applies in risk assessment of existing chemicals, no uniform prescriptions can be given for the risk management either. These high production volume chemicals normally have been on the market for many years and serve many purposes in various areas. In order to reduce the risks of these chemicals, quite different measures have to be applied. Moreover, the amount of information available differs considerably from chemical to chemical and from use pattern to use pattern. Therefore, the Technical Guidance Documents for Risk Reduction Strategies of the EU allow a large amount of flexibility in order to select the most appropriate risk reduction strategy. While such an analysis should be driven by the criteria effectiveness, practicality, economic impact and monitorability, the scope of such an analysis is not exactly prescribed. In analysing the advantages and drawbacks of chemical substances one should usually start with qualitative considerations and then proceed with quantitative cost-benefit calculations, including extensive monetarisation of human life or the environment only when necessary and when the information needed can be obtained with reasonable expenditure of time and costs. Indeed, the first three substances on the EU priority list for which cost-benefit analyses have been performed vary considerably (DEGBE and DEGME on the one hand, and short-chain chlorinated paraffins on the other).

Risk Reduction Measures for the First Three Priority Substances of the EU Existing Chemicals Regulation

For 2-(2-butoxyethoxy)ethanol (DEGBE) and for 2-(2-methoxyethoxy)-ethanol (DEGME), the risk assessment reports stated well defined risks to consumers as well as workers, but not to the environment. Therefore the recommended risk reduction measures are relatively easy to enforce and will have low economic impacts: additional labelling, more information on the Material Safety Data Sheets (e.g. use of protective clothing), development of an indicative occupational exposure limit value, phasing out use in paints developed for spray applications. The latter measure should be laid down in a voluntary agreement between producers, importers and the trade organisations representing the formulators of the substances.

In contrast to DEGBE and DEGME for short-chain chlorinated paraffins, which are used in a wide variety of applications, a risk is apparent from the assessment of a large number of local scenarios. Therefore, possible risk reduction measures are very complex, and difficult to enforce and to monitor. For two of the main risks, i.e. use in cutting fluids in the metal working industry and use in the leather industry, very comprehensive cost-benefit analyses have been performed by the UK. In accordance with the Technical Guidance Documents for Risk Reduction Strategies of the EU, a tiered approach was applied by first conducting a qualitative risk-benefit analysis to preclude the two least effective options, followed by a qualitative (benefits) to semi-quantitative (costs) analysis to identify the most effective of the remaining options.

As this study will be discussed in another contribution to this workshop, I do not want to discuss it in greater detail here. I only want to make a few comments from our point of view, which show that even within the framework of such an extensive study the problems involved in attempting to quantify costs and risks cannot be solved completely. Aside from all the aspects which are basically impossible to quantify or where there is no consensus about their valuation in monetary terms (e.g. environmental benefits), the long list of parameters which can be quantified could and should be extended to include additional aspects. Cases in point are the significant costs (compared to non-chlorinated substitutes) of high-temperature incineration of chlorinated waste or of dealing with dioxin-related problems that are encountered when chlorinated waste is treated otherwise. In general, we think that as long as it is impossible to apply a quantification or monetarisation to every aspect of the study, the conclusion in form

of a cost/benefit analysis is necessarily limited. There is always the danger, that a higher percentage of the costs than of the benefits are covered. In addition, in the special case of short-chain chlorinated paraffins calculating the costs incurred by industry to replace those substances appears questionable as other EU Member States have phased out chloroparaffins already. Beyond the scope of the analysis, but with respect to arguments relating to the EU Directive on restrictions on marketing and/or use, we consider the following as noteworthy: the replacement costs already paid by progressive enterprises are a competitive drawback for these advanced enterprises themselves rather than for enterprises which refuse to incur such replacement costs in the present market situation. The progressive companies have already internalized the external costs, which occur due to the risks for man and the environment from the use of this dangerous substance. As a consequence, restrictions on marketing and use eventually would remove obstacles to trade.

Questioning that it is possible to balance costs and benefits in quantitative terms satisfactorily, does, however, not mean that a semi-quantification is useless. The risk reduction strategy for chlorinated paraffins is in our view an excellent example for a comparison of different possibilities to reduce the risks described in risk assessment report.

Cost-benefit Analysis

Although elaborating quantitative cost-benefit analyses appears to be a great challenge as well as an ultimate goal of the decision making process, in reality especially we who work in the field of environmental protection are usually faced with the situation that for only a few parameters is the information needed actually available or can it be obtained with reasonable expenditure of time and costs. In addition, due to the high proportion of intangible costs and benefits as well as the inherent need for preliminary political decisions, the results obtained in such analyses must be interpreted with caution. This, together with the need to select just a limited number of the total advantages and drawbacks for quantitative assessment, opens the door for all kinds of manipulations. Depending on the particular interest, almost any result can be "designed". Often, political preliminary decisions or presumptions are presented in the guise of mere technical cost-benefit analyses.

At a recent workshop on risk reduction measures organised by the EU commission, DG III, in Brussels, Professor Krüger from the University of Wuppertal gave a number of examples of how the selection of parameters and premises will influence the outcome of the analysis. One important parameter is the time scale to be regarded when the costs of any measure are estimated. Other aspects which influence the result of the analysis and which are often neglected are a number of external effects, including positive aspects of risk reduction measures on the technical progress. He especially stressed the possibility for the outcome of such analyses to be influenced by the choice and weighting of certain intangibles. He gave the following example: In a study on the economic effects of accidents and occupational diseases, the result turned out to suggest that prevention would not pay. The authors did not wish to publish this result. So they decided to include "quality of life" as a factor on the benefit side. Their argument was that by being ill the people suffered a loss of "quality of life" that they valued with the patient's contribution to national product. After adding this quality of life factor, the overall result of the study reversed: prevention will pay.

Similar problems arise when a comparison with possible substitution products has to be performed, in which little information and experience is usually available. Here, the positive aspects of a conversion to alternative substances or technologies should by no means be underestimated. As mentioned above, the cost-benefit analysis for chlorinated paraffins is an example which illustrates these problems very well.

Moreover, a comprehensive quantitative cost-benefit analysis may be an extremely time-consuming process, with the consequence that necessary decisions on risk reduction will be postponed.

Cost-efficiency Studies and the Utility-Value Method

Due to the problems discussed, we think that cost-efficiency (or effectiveness) studies - i.e. a comparison of alternative approaches to reach a specific goal - in many cases should be the procedure of choice. Using this method, the reduction of the ecological risk is taken as a science based goal which should be reached by the most efficient means. Questioning the result of the risk assessment, which in essence is a derivation of specific PEC/PNEC ratios, is to be avoided. Each PEC/PNEC ratio above 1 is understood as a risk to be reduced. From our point of view, the aim of the consecutive risk reduction strategy is to reduce the PEC below the PNEC and to evaluate the most efficient way to achieve this goal. Up to this point, the introduction of eventually political arguments like too high costs for society or industry will muddle the analysis.

In a comprehensive evaluation Professor Winter, university of Bremen, and co-workers come to the conclusion that qualitative and semi-quantitative analysis is required and sufficient. The choice between alternatives is often possible on the ground of simple trend analysis. Monetisation is only illuminating if reliable data exist and the moral value element in assessing the pertinent parameter is negligible. The uncertainty incorporated in the analysis must be acknowledged. The authors conclude that neither a pure cost-benefit-analysis nor a pure cost-effectiveness-analysis but a combination of both should be applied. Their suggestion could serve as a bridge between the anglo-american approach of balancing costs and benefits and the continental precautionary principle.

When the most efficient way to reduce the environmental concentration of a dangerous substance has been identified as a result of cost-efficiency studies, the associated costs may still be higher than what society is able or willing to pay. In these cases, political decisions have to solve the problem and should be clearly pointed out as political decisions.

If the measures under consideration contribute to a different extent to a reduction of risk for man or the environment, a method of valuing these different benefits has to be found. The so called **utility-value method** permits evaluating benefits in non-monetary terms, in such a way that benefits of different measures can be compared with each other. Using this method, the most important goals of a given measure are compiled in a multi-dimensional system. Then several alternatives are examined, in order to find criteria for the valuation of the alternative's contribution towards the goals and to weight these criteria according to their importance. The contributions of each alternative are transformed into scaled degrees of contribution to the goals and are multiplied by the weight factors, resulting in utility values for each alternative. This method has the advantage that it reveals preferences and thus can help to make political decisions more transparent. If all parties concerned agree on a weighting scale and accept the results of the analysis, then there is just one decision.

Case Studies

In the literature only a few examples of comprehensive cost- effectiveness or cost-benefit-analysis are given. I want to mention the following ones.

The first example deals with a project concerned with water pollution control measures. It describes the results of a study on the possibilities to reduce the release of nitrogen into the "Obere Leine" (a small German river) area. The following alternatives were compared:

- wastewater treatment
- sewer rehabilitation
- reduction of the use of fertilisers in agriculture.

The results showed that cost-effectiveness analysis is a suitable method to make different measures comparable. Due to the high standard already achieved in wastewater treatment and due to the high rate of connection to wastewater treatment plants, the use of measures in the field of wastewater treatment to achieve a further increase in water quality would be associated with relatively high costs. In contrast, relatively small changes in the use of fertilisers in agriculture lead to large reductions in the release of nitrogen: Whereas in "normal" agriculture 20 kg nitrogen are released per ha and year to surface water, by changing to ecological agriculture a reduction to 5 kg nitrogen per ha and year could be achieved. This measure costs 6 Euro for the reduction of each kg of nitrogen. For comparison, a similar nitrogen reduction through wastewater treatment would result in costs of 10 Euro/kg nitrogen.

The study showed that a considerable reduction in the release of nitrogen is possible, and that this benefit in comparison with other alternatives can most effectively be achieved by a change in agricultural practice.

In a second case study, investigations were undertaken to identify the most efficient way to reduce the contamination of groundwater by chlorinated hydrocarbons from 49 contaminated sites in Hannover. A prerequisite in this study was that there is not enough money available to clean up all contaminated sites. Therefore, the question to be answered was in which way the largest effects can be achieved with the least costs. The result was that it is far more effective to begin rehabilitation with those sites where emissions are higher rather than to first close a number of smaller emissions. Assuming that 20 million DM is available, in the former case the release of chlorinated hydrocarbons to the groundwater could be reduced by 50% from 3 t/a to 1.5 t/a, whereas in the latter case the reduction attainable with the same amount of money could only amount to 15%, to still more than 2.5 t/a.

I think that these relatively simple examples provide a rough picture of how the method of cost-effectiveness analysis can be used to support decision makers in risk management.

Literature

- 1) Wolfgang Krüger: Problems of economic evaluation of risk reducing measures. Contribution to the Second Workshop on Risk Management in the Framework of Council Directive 76/769/EEC - Brussels 17/18.11.1997.
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- 3) Joachim Kreuzburg, Udo Müller: Volkswirtschaftliche Effizienz von Maßnahmen zum Gewässerschutz - Erarbeitung von Bewirtschaftungsstrategien für makroskalige Planungsräume. Korrespondenz Abwasser 1997, 220 - 238.
- 4) Elke Genschow, Rolf Mull: Kosten-Wirksamkeits-Beziehungen als Bewertungskriterium für Maßnahmen zur Verbesserung der Gewässergüte. Korrespondenz Abwasser 1997, 239 - 248.

Assessment of Draft Legislation¹

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Summary

Legislation is intended to reduce the risk of an undesirable outcome or harm, and should therefore be assessed to ensure that this is accomplished with an appropriate balance between costs and benefits. A regulatory appraisal methodology is presented which includes the following steps: risk assessment, compliance cost assessment, cost-effectiveness and risk trade-off analysis, socio-political analysis. When applied to three specific European environmental regulations or directives, it appears that the proposed measures are non-optimal, either for the environment or the economy.

To improve the quality of Community legislation, a regulatory appraisal, based on risk assessment and the cost-benefit analysis process, should be introduced by the European Commission, as implied by the Treaty of Amsterdam. A successful implementation will rely on an extensive consultation of all stakeholders and on an integrated environmental approach, with clear and quantified quality objectives for air, water, soil and waste to allow sound legislative priorities to be set up.

Main Goals of Assessment of Draft Legislation

Legislation is one of the options to reduce the risk of an undesirable outcome or harm. Draft legislation should therefore be assessed to ensure that the regulation is necessary, aimed at the right target, in proportion to the problem, and reaches the objective of an appropriate balance between costs and benefits. To do so, the UK Government has developed a regulatory appraisal process² incorporating an assessment of both the risk and of the cost to comply with the proposed solution which relies on three key principles:

- Think small first
- Proportionality
- Focus on the goal

Paradoxically, some of the most well intentioned efforts to reduce identified risks have quite often turned out to increase other risks. Draft legislation should therefore be assessed to ensure that efforts to combat a "target risk" do not unintentionally foster increases in "countervailing risks". Compared to the target risk, countervailing risks can be of the same or different types and can affect the same or different populations. A framework for "risk trade-off analysis" has been proposed by John D. Graham, Director of the Harvard Risk Centre³ and included in the US "Framework for Environmental Health Risk Management".⁴ Researchers in the social sciences^{5,6} insist on the limits of this rational approach to risk management and give us some cues for the social construction of risk acceptability, based on a large consultation of stakeholders to better understand their values and concerns.

A regulatory appraisal methodology combining the above approaches could be:

- Risk assessment:
 - ◇ Identify the problem and the harm
 - ◇ Estimate the risk associated with the harm
 - ◇ Identify the options for dealing with the harm
 - ◇ Estimate the impact (and effectiveness) of the options on the target risk
 - ◇ Assess the eventual countervailing risks of the options
- Compliance cost assessment:
 - ◇ Public (consumer, taxpayer)
 - ◇ Administration
 - ◇ Economic operators
- Risk trade-offs and cost-effectiveness analysis
Socio-political analysis:
 - ◇ Analyse stakeholders' disparities of risk perception and risk management priorities
 - ◇ Set the criteria on which risk acceptability or tolerance should be judged
 - ◇ Determine the trade-offs between criteria

Three draft legislative acts are examined in this paper: the proposed Directive on solvent emissions, a Decision for methyl bromide phase-out, and the proposed Directive on End of Life Vehicles (ELV). In each case, it is clear that the use of Member State (MS) resources is not optimal, resulting in a competitive handicap for the European economy and with negative side effects for public health or the environment. The main reason has been the lack of a good quality dialogue between stakeholders.

The Proposed Solvent Emissions Directive: "*Think small first*"

This proposal concerns the limitation of emissions of volatile organic compounds (VOCs) due to the use of organic solvents in certain industrial activities; it has been approved by the Commission and is being analysed by the European Parliament.

Risk Assessment

Identify the problem

- Nitrous oxides (NO_x) and VOCs (precursors), with the action of sunlight, can cause ground level ozone peaks (a primary constituent of urban smog), potentially leading to respiratory difficulties (asthma).

Estimate the risk

- Asthma is a disturbing health problem, particularly for children.
- On a global scale (northern hemisphere), emissions of VOCs (90% natural + 10% anthropogenic) contribute to 25% of ozone formation in the troposphere.
- On a local scale, ozone peaks occur mainly between May and September.
- The main anthropogenic VOC sources in Europe are traffic (45%), solvent usage (30%),⁷ other (25%).
- Peaks depend a great deal on local conditions and are limited to specific areas (Paris, Marseille, Strasbourg, London, Rotterdam, Milan, Athens, etc.).

Identify options

1. Do nothing, since VOC and NO_x emissions are already sufficiently regulated by:
 - ◇ the Integrated Pollution Prevention and Control (IPPC) Directive, which will include VOC emissions of large industrial users of solvents (> 200 T/year)
 - ◇ the Auto Oil Directive for transport
 - ◇ the revised large combustion plant Directives.

Furthermore, solvent emissions can be reduced by other means than "command and control" legislation. Under the "Responsible Care" Program, chlorinated solvent emissions by surface and dry-cleaning activities have been reduced in Europe by 75% for the 1974-1996 period (and 39% between 1992 and 1996)⁸ (see Figure 3).

2. Limit the measures to significant solvent users and to areas where ozone peaks do occur and assign to each MS an objective for VOC emissions, based on a realistic air quality standard (that is, an ozone concentration of 90 ppb (1 hour), as adopted by the Auto Oil Directive).
3. Impose detailed rules for each industrial sector applicable to all MS, to all solvent using enterprises and to all areas of the EU or give the choice to each MS to design a National Plan to reach the same objective, independently of their respective air quality levels.

NB - Option 3 has been retained by the Commission.

Estimate the impact (and effectiveness) of the options on the risk

- *Option 1*: will contribute to reduce local pollution, but might not be sufficient to eliminate ozone peaks
- *Option 2*: would eliminate all harmful ozone peaks
- *Option 3*: will further reduce global pollution, but will impose an unnecessary burden on countries with low VOC emissions without any significant air quality improvement, compared to Option 2.

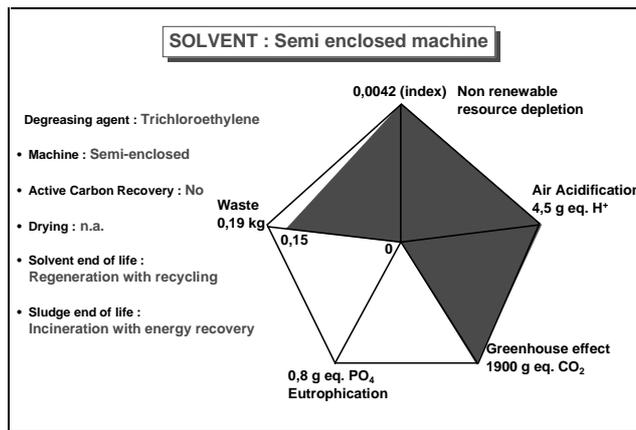
Assess eventual countervailing risks of the options

- *Public Health*

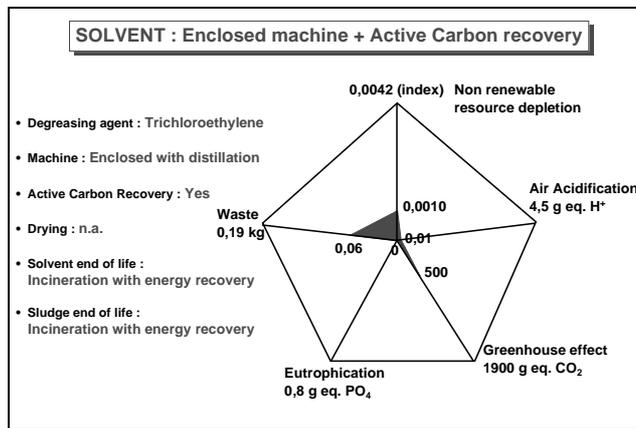
If ozone is associated with respiratory problems, it also screens harmful ultraviolet rays whether in the troposphere or stratosphere. In the framework of the US Clean Air Act (reduction of ground level ozone by 10%), it has been estimated that the proposed reduction of ozone would increase malignant melanoma (130-160 cases of cancer/year), non-melanoma skin cancers (2 000-11 000 cases) and new incidences of cataracts (13 000-18 000 cases), exceeding the EPA's most optimistic estimate of the health benefits of reducing asthma by more than 300 million US dollars per year.⁹

- *Environment*

Solvents used in industrial applications such as metal degreasing (see Figure 1 - scenario 1) could be substituted by water based solutions with a negative impact on water quality¹⁰ (scenarii 4 and 6), while technology based on solvents with active carbon recovery has a much lower environmental impact: scenario 2 has indeed a minimal impact on both non-renewable resources, air quality (acidification and greenhouse effect), water eutrophication and waste production.

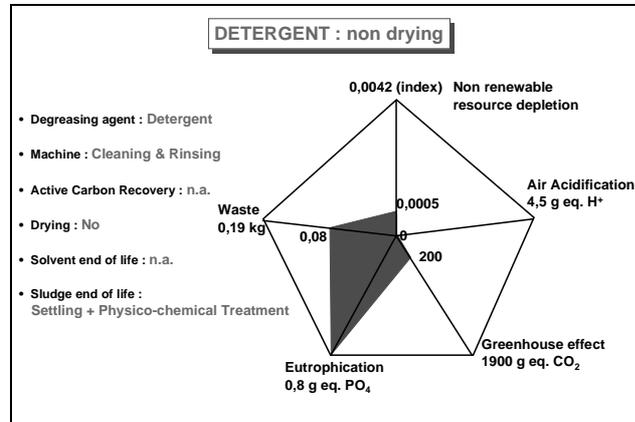


Scenario 1

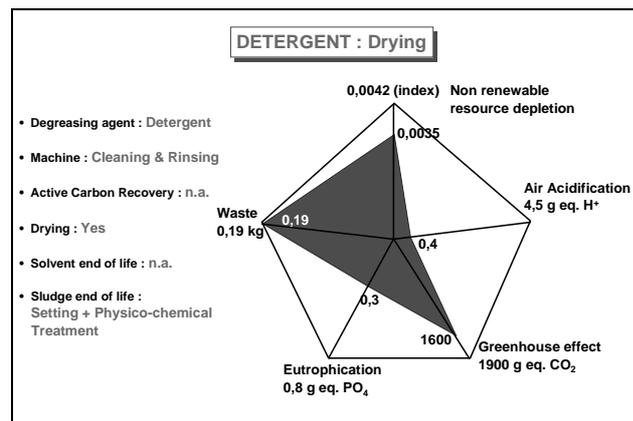


Scenario 2

Figure 1: Environmental impact of metallic parts degreasing



Scenario 4



Scenario 6

Figure 1: Environmental impact of metallic parts degreasing

Compliance Cost Assessment of Option 3

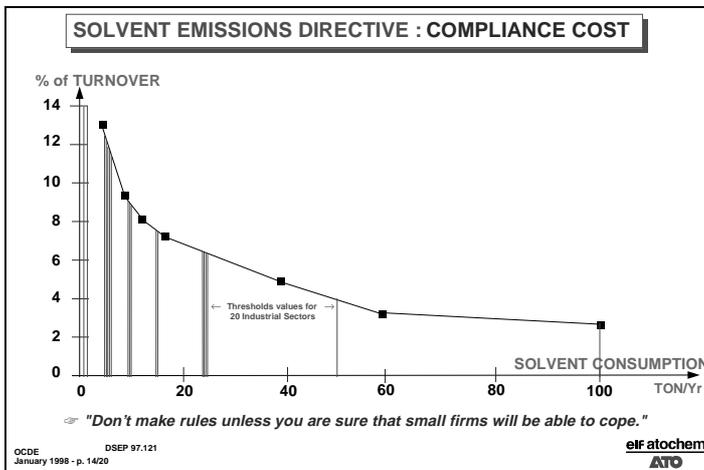


Figure 2

- Business sectors affected: 20 industrial sectors, 400 000 enterprises employing 10 million people
- Total cost: 70-80 billion ECU over 20 years (with an initial capital investment cost of 30 billion ECU) for a reduction of 1.4 million tonnes per year of VOCs
- Compliance costs for business (average cost/tonne of avoided VOC emission):

ECU / T

All enterprises: 2 960

SMEs: 11 250

The compliance cost represents between 3 and 13% of turnover for SMEs, depending on solvent consumption (respectively 100 and 5 tonnes/year) (see Figure 2).

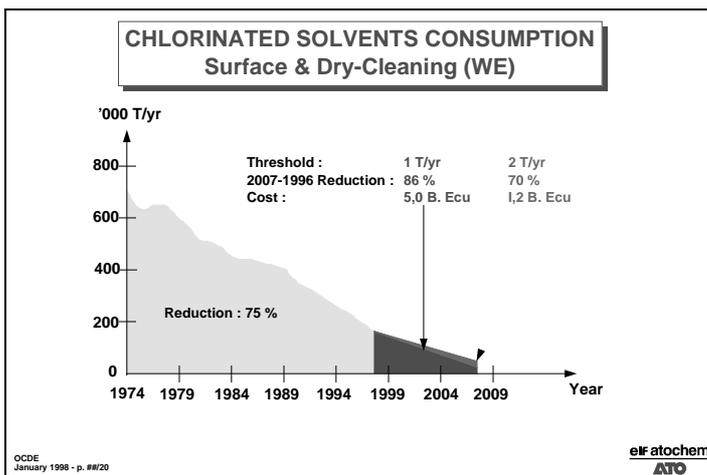


Figure 3

Risk trade-offs and cost-effectiveness analysis

- Option 2 achieves the desired outcome of eliminating ozone peaks.
- Option 3 does not bring any significant improvement in air quality, will eliminate many small firms from the business, and might have negative side effects on public health and the environment. For the EU Social and Economic Committee, this option needs to be justified from a cost-benefit perspective.

It is obvious that Option 2 is considerably less expensive.

"Don't make rules unless you are sure that small firms will be able to cope"¹¹

For some industrial sectors, the threshold values apply to solvent consumption as low as 1 tonne/year. In the surface cleaning sector, where consumption has already been reduced by 75%, a threshold value of 1 tonne/year will permit a further emissions reduction of 86% for a capital cost of 5.0 billion ECU. The industry proposes to increase the threshold value to 2 tonnes/year, still allowing a further reduction of 70% for a capital cost of 1.2 billion ECU only (see Figure 3).

Regulation for Methyl Bromide Phase-out: "Proportionality"

Risk Assessment

Identify the problem

- Methyl bromide is a crop protection agent with a large spectrum of action (fungicide, nematocide, insecticide, herbicide) allowing productivity gains of 25-40% for production of tomatoes, strawberries, melons, lettuce, flowers, etc.
- Methyl bromide contributes to stratospheric ozone depletion (ODP ~ 0.3; lifetime: 0.5 - 0.9 years)

Estimate the risk

- World-wide methyl bromide emissions represent 160 000 tonnes/year:
- 75% are natural emissions: oceans, natural fires (120 000 tonnes/year)
- 25% are anthropogenic emissions (40 000 tonnes/year)
- 35 000 tonnes/year from field fumigation (half of the world production of 70 000 tonnes/year) is adsorbed onto the soil and thence biodegraded, the other half being emitted.
- 5 000 tonnes/year from vehicles

Identify options

Table of Montreal and EU phase-out schemes

- 1 - Reduce emissions by application of plastic Virtually Impermeable Films (VIF) in the fields.
- 2 - Follow the production phase-out, as decided by the Montreal Protocol.
- 3 - Accelerate the phase-out in EU.

<i>Reduction in production</i>	<i>Montreal</i> ¹²	<i>EU</i>
25%	1999	1998
70%	2003	
100%	2005	

NB -The EU Commission has proposed Option 3 (25% reduction in force for 1998; phase-out in 2001 still under discussion)

Estimate the impact (and effectiveness) of the options on the risk

Option 1: would reduce the anthropogenic emissions by more than an additional 50%.

Option 2: would progressively reduce the emissions to zero and give sufficient time to develop substitutes

Option 3: will be environmentally and financially disadvantageous compared to Options 1 and 2. Today, there is no substitute for methyl bromide with such a large spectrum of action and any substitute which exists may incur extra costs or environmental risks. Moreover, the EU production of fruits and vegetables will be replaced to some extent by imports from Morocco, Tunisia and Kenya, which will apply methyl bromide produced outside Europe on their crops;¹³ emissions will thus be transferred from the EU to the Maghreb, with no net change for the environment.

Compliance cost assessment of Option 3

- Cost: 1.8 billion ECU/year, resulting in an increase in the cost of vegetables to the consumer and transfer of production to outside EU.
- Business sectors affected: 90 000 jobs in Greece, Italy, Spain, Portugal and France.

Risk trade-offs and cost-effectiveness analysis

- Option 3 reduces competitiveness of Southern European producers of fruits and vegetables with doubtful environmental benefit.
- Option 2 combined with Option 1 would have a lower environmental impact and would not jeopardise EU economic interests.
- Option 1 would have been sufficient at the level of the Montreal Protocol discussions.

"Don't make rules unless the benefits really justify the cost imposed on business and others."¹⁴

End of Life Vehicles Proposed Directive: "Focus on the goal"

Risk Assessment

Identify the problem and the harm

- 25% of the materials in End of Life vehicles (10 million ELV per year) end up in landfills:
 - ◊ 10% glass
 - ◊ 7.5% plastics
 - ◊ 5% rubber
 - ◊ 2.5% miscellaneous, including hazardous substances (heavy metals, PCB's, chorofluorocarbons, etc.)
- The remaining 75% of the materials (ferrous and non-ferrous metals) are recycled.

Estimate the risk

- Automotive shredder waste (2.25 million tonnes per year) represents only 0.1% of the total waste stream, but takes up valuable space in landfills and might result in a sub-optimal usage of non-renewable resources.
- There is no risk to human health for the materials (e.g. glass, plastics and rubber) which are inert, but the hazardous materials fraction (which accounts for up to 10% of total EU hazardous waste) should not end up in landfills.

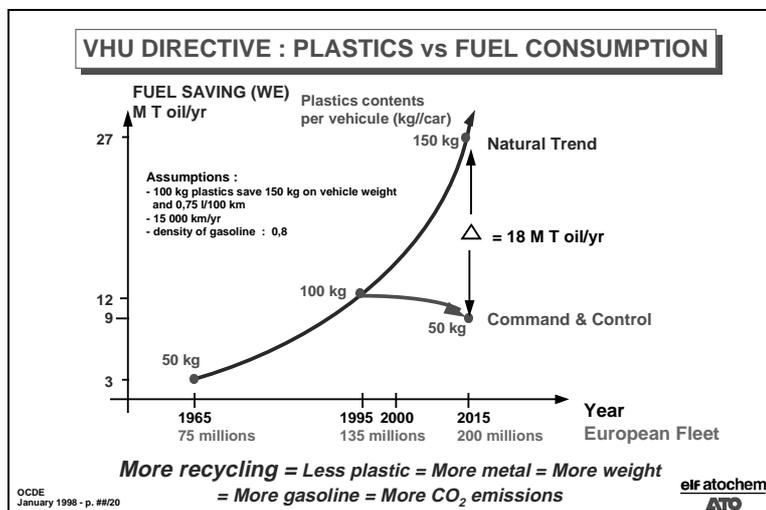
Identify options

1. Do nothing more than today
2. Reduce progressively materials going to landfill from 25% to 5% and leave each MS to decide how to achieve that goal (material recycling and/or energy recovery)
3. Specify to MS detailed prescriptive regulation on how to achieve the goal specified in Option 2:
 - 80/85% material recycling by the year 2005 / 2015
 - 5/10% energy recovery " "

NB - Option 2 has been retained by several MS on the basis of voluntary agreements. Option 3 is being considered by the proposed directive, adopted by the European Commission in mid-1997.

Estimate the impact (and effectiveness) of the options on the risk

- Option 1 is an alternative for MS with no landfill limitation, on the condition of withdrawing hazardous materials before sending the shredder waste to landfill.
- Options 2 and 3 both achieve the goal of reducing discharge to landfills
- Option 3 is based on an a priori hierarchy between recycling and energy recovery and cannot be demonstrated to be better for the environment in general.

Assess eventual countervailing risks of the options**Figure 4****Compliance cost assessment**

- Material recycling is done economically for metals and for bulky, easy to dismantle, non-metal parts (bumpers, windshields, etc.).
- For small, non-removable parts, plastics recycling is expensive and energy recovery is preferable (cement kilns, for instance).

NB - A detailed cost assessment still must be done, but Option 3 will likely be at least twice as expensive than Option 2.

Risk trade-offs and cost-effectiveness analysis

It has not been proven that Option 3 is technically feasible or better for the environment than Option 2. In the case of plastic packaging recovery from municipal waste, it has been demonstrated¹⁶ that the optimal solution from an environmental point of view is to recycle only 18% of the plastic waste and to incinerate with energy recovery 53%.

Don't make detailed prescriptive regulations when you can simply specify the goal and allow business to decide how to achieve it."¹⁷

Recommendations for Environment Regulations

Problems that must be overcome in the field of EU environmental regulation

- Draft legislation remains too often influenced by **ecological ideology and perception of risk**, rather than based on an in-depth scientific assessment of risk and environmental impact.
- **Risk assessment, cost-effectiveness, and risk trade-off analysis, if any, come too late** in the legislative process and are poorly communicated.
- **Consultation of the stakeholders** (scientists, NGOs, the public, economic operators, etc.) to assess the risks, the costs and the effectiveness is often **inadequate** and the results are often insufficiently regarded by the decision makers.

Means to be used

- A **regulatory appraisal**,¹⁸ **with an assessment of the risk and of the cost of compliance**, should be systematically prepared **prior to drafting** any new regulation.
- Risk assessment should include an **evaluation of the environmental impact**, based on a **life cycle assessment (LCA)** and a **multimedia approach** (air, water and soil together rather than separately), along with a risk trade-off analysis (especially in the case where substitutes are recommended to phase out a product).
- Compliance cost assessment should take into consideration the **burden on the public** (consumer, tax payer), the administration and the economic operators and the possible **loss of competitiveness** of the European economy.
- A **dialogue between stakeholders** should be organized to understand their values, their criteria for risk acceptability, and to share their different perceptions of risk and their priorities for risk management.

Possible strategies for application of assessment (Figure 5)

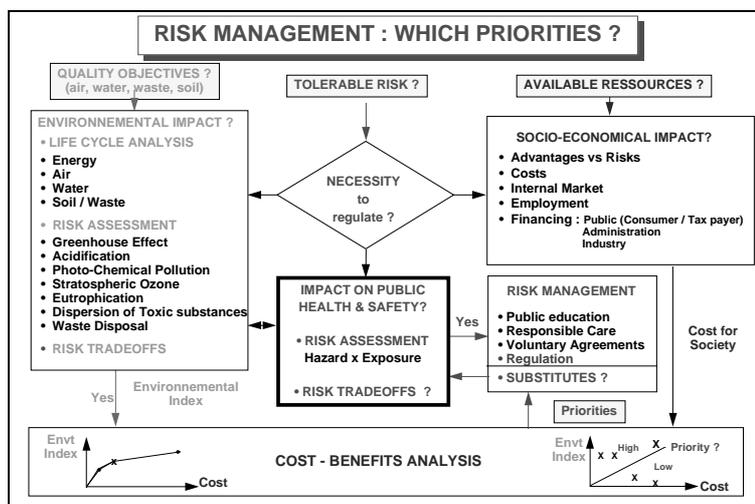


Figure 5

Absolute maximum levels of risk protection relative to safety and health of employees and public should be established and imposed, irrespectively of cost.

Environmental quality objectives for air, water, soil and waste should be determined by each MS and consolidated at the EU level; combined with LCA, this would allow priorities to be put in place for draft environmental legislation, by comparing compliance cost with environmental gain.¹⁶

How to move forward?

- The need for a systematic cost-effectiveness analysis of legislative proposals has been widely recognised.¹⁹ The Treaty of Amsterdam states in the Protocol on the application of the principles of subsidiarity and proportionality that:

"The Commission should:

- *consult widely before proposing legislation and, wherever appropriate, publish consultation documents;*
- *justify the relevance of its proposals with regard to the principle of subsidiarity ...*
- *take duly into account the need for any burden, whether financial of administrative, falling upon the Community, national governments, local authorities, economic operators and citizens, to be minimized and proportionate to the objective to be achieved..."* (Chapter 9)

Thus, the Commission must take into account the financial and administrative burden (*cost*), which must be minimized and proportionate to the objective (*benefit*). Therefore, there is an inclusion of the principle of **cost-benefit analysis as a legal requirement** of the Commission.

Structured approaches, such as the one described, incorporating an assessment of both the risk and the cost to comply with the proposed solution, have proven to be beneficial and should be systematically implemented.

- **Increased transparency and consultation** are two important requirements of the Treaty (Chapter 10), and decisions must now be taken "*as openly as possible*" and "*as closely as possible to the citizen*".
- In the Declaration to the Final Act on the **quality of the drafting of Community legislation** (Chapter 11):

"The Conference notes that the quality of the drafting of Community legislation is crucial if it is to be properly implemented by the competent national authorities and better understood by the public and in business circles... Therefore, the Conference declares that the European Parliament, the Council and the Commission ought to establish by common accord guidelines for improving the quality of the drafting of Community legislation..."

A legal basis has been set up in the Amsterdam Treaty to improve the quality of environmental regulations. It is up to all stakeholders (Commission, scientists, NGOs, public and economic operators) to make it a reality and find the right balance between the environment and the economy in order to progress towards sustainable development.

Footnotes

1. This is an update from papers presented at the Workshop "The Quality of European and National Legislation and the Internal Market" organized by the Ministry of Justice of the Netherlands and the European Commission in The Hague, 23rd-24th April 1997 and at the conference "Challenges of Responsible Risk Management" organized by ECN and the Weinberg Group in Brussels, 6th-7th October 1997.
2. "Regulation in the Balance: A Guide to Regulatory Appraisal Incorporating Risk Assessment" and "Checking the Cost of Regulation: A Guide to Compliance Cost Assessment" by the UK Cabinet Office Quality Regulation Unit (formerly Deregulation Unit).
3. "Risk versus Risk: Trade-offs in Protecting Health and the Environment" by J.D. Graham and J. Baert Wiener - Harvard University Press.
4. The Presidential/Congressional Commission on Risk Assessment and Risk Management - Final Report - Volume 1 - 1997.
5. "The Challenge of Credible Risk Calculations" - O. Renn - Director, Centre of Technology Assessment - Baden-Württemberg.
6. "Acceptability of risk: Individual choice and social construction" - Gilles Heriard Dubreuil - TRUSTNET European Seminar - Paris - October 22, 1997.
7. If industrial solvent emissions were reduced by 100%, it is estimated that ozone formation in the troposphere would be reduced by approximately 0.75% (0.75% = 30% solvent usage x 10% anthropogenic x 25% VOC contribution).
8. This was made possible with the signature of 50 charters of co-operation between the European Chlorinated Solvent Association (ECSA) and individual companies, distributors, user or recovery trade associations, resulting in improvements in machines enclosure, more efficient use of solvents, improved recovery or handling.
9. W.G. Gramm, former Administrator of the Office of Information and Regulatory Affairs at the US Office of Management and Budget - The Wall Street Journal - June 9, 1997.

10. Life Cycle Assessment: An environmental comparison of trichloroethylene and aqueous solutions for metallic parts degreasing - by ECOBILAN S.A.
11. Former Prime Minister John Major - Foreword to the Guide to Regulatory Appraisal.
12. Reduction program for "Article 2 countries" - For "Article 5 countries": 20 % reduction in 2005 and phase out in 2015.
13. European Methyl Bromide Association - April 1995.
14. Former Prime Minister John Major - Foreword to the Guide to Regulatory Appraisal.
15. $200 \text{ million vehicles} \times 0.75 \text{ litre/100 km} \times 15 \text{ 000 km/year} \times 0.8 \text{ kg/litre} = 18 \text{ million tonnes of gasoline thanks to 2 million tonnes of plastics.}$
16. "Disposal of Household Waste: Analysis of Environmental Impacts and Costs" - H. Sas, Centre for Energy Conservation and Environmental Technology, Delft, the Netherlands - November 1994.
17. Former Prime Minister John Major - Foreword to the Guide to Regulatory Appraisal.
18. The DG III is taking such an initiative: Risk Management Workshops organized in January and November 1997.
19. See "The Need for Cost Benefit Analysis" - Belmont European Policy Centre - September 1996: 18th Declaration of the Maastricht Treaty, Westendorp Reflection Group, Competitiveness Advisory Group to the Florence European Council, the Commission: Sutherland High Level Group, Monitor Report, the European Parliament, the Economic and Social Committee, UNICE, the European Round Table, OECD.

Risk-Benefit Analysis of Existing Substances

Elizabeth Surkovic
Chemical Industries Association
United Kingdom

This presentation seeks to demonstrate the way in which government and industry have worked together in the UK to develop pragmatic solutions. In this specific case, representatives from industry and government had identified the need for an outline framework for the development of a risk-benefit methodology. Whilst the Group was established as a joint government/industry Group, it was Chaired by an independent third party, Prof. Peter Calow of the Institute of Environmental Sciences and Technology. The Group comprised economists from government and chemical control managers from industry. The methodology took about 18 months to prepare, and materials were taken from existing work in the USA and from specific experience on substances. The resultant framework for the development of a risk-benefit methodology was derived from welfare economics.

The framework which the Committee developed was submitted to the Commission of the European Union as a “thought starter” in developing EU wide guidance. This presentation summarises the methodology developed.

Introduction

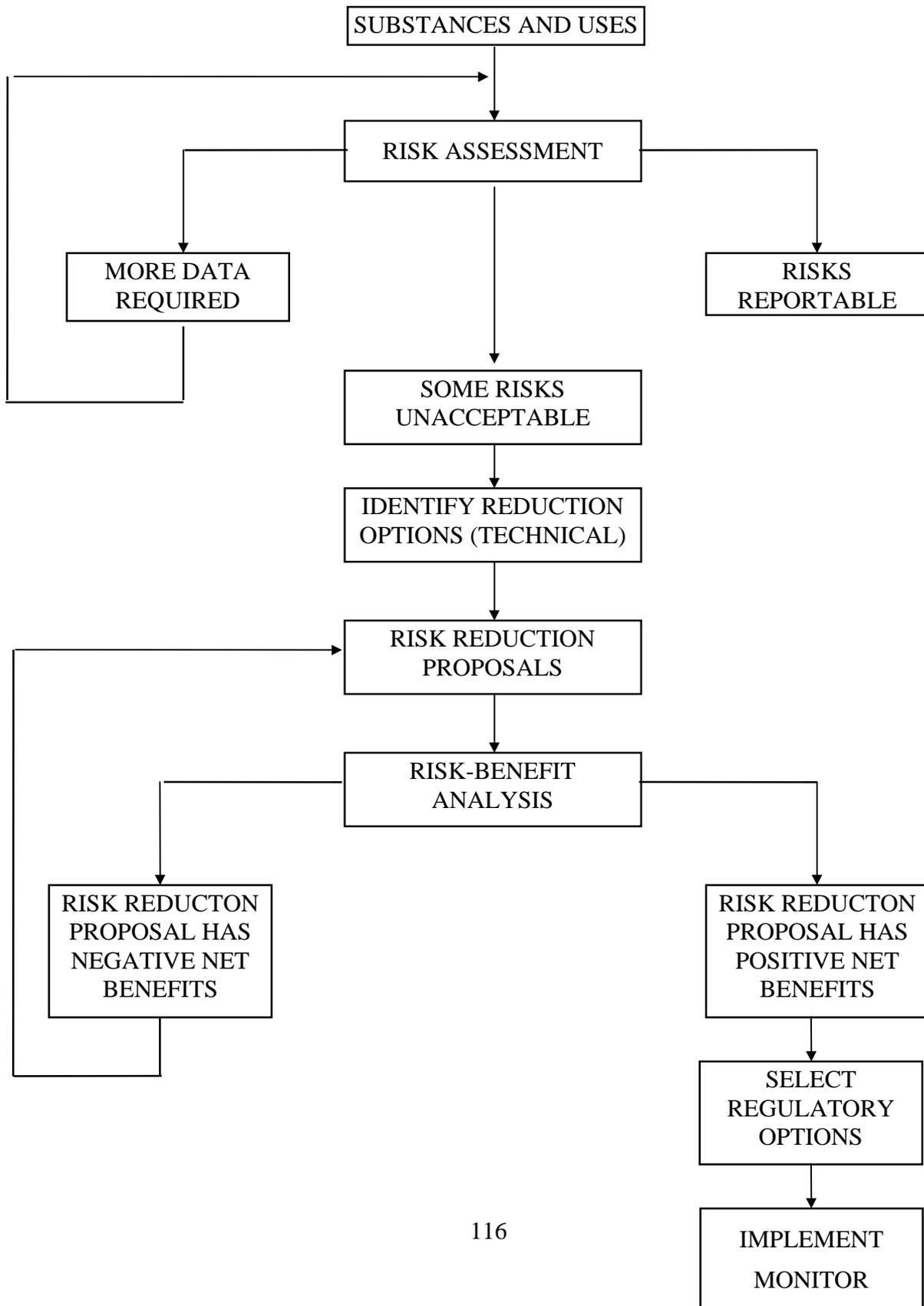
The purpose of this presentation is to summarise, for the use of the risk-benefit practitioners and others, the steps to be taken in producing risk-benefit and cost-benefit analyses. The original paper was prepared in the context of the European Existing Substances Regulation 793/93.

Six steps in risk-benefit analysis have been identified, and these are summarised in the centre blocks of Figure 1.

The identification and weighing up of the costs and benefits associated with the different technical options for control can be carried out to various levels of detail and precision, ranging from the completely qualitative to the fully quantitative. Three examples of options along this spectrum were identified for existing substances:

- 1) a qualitative risk-benefit analysis;
- 2) a quantified risk-benefit analysis;
- 3) a cost-benefit analysis.

Figure 1 The steps in risk benefit analysis required by the Existing Substances Regulation 793/93. The six steps referred to in the text are the ones in the centre blocks.



Three general criteria will determine how far to go along this spectrum:

- 1) Can a sensible and logical way forward be found?
- 2) Are the required data available or can they be made available at reasonable cost?
- 3) How expensive are further investigations and data collection likely to be in terms of skilled manpower, etc. in relation to the intrinsic importance of the issue to be addressed?

No matter how far the analysis is taken, the central question remains: how do the benefits to human health and the environment expected from introducing controls on existing substances compare with the socio-economic costs to industry and consumers?

Risks to Human Health and the Environment and their Valuation

The starting point for valuing risks to human health and the environment will be the risk assessment. A significant problem in characterising risks is that the output of risk assessment as required by the Existing Substances Regulation 793/93 will generally be in the form of risk quotients that compare expected doses and environmental concentrations with predicted no effect levels, i.e. the ratios PEC/PNOAEL and PEC/PNEC.

Two points can be made on the outcome and report of this risk assessment exercise which are relevant to the identification and weighing up of costs and benefits of different control options. First, the components of the risk quotients are likely to be based on historical data that will often be no more extensive than base-set requirements (as specified in Directive 67/548 EEC). Hence the risk assessment data will be limited in amount and of variable quality.

Second, this is not a fully quantified risk assessment in that it does not lead to probability statements. Hence there is still much uncertainty on how the quotients translate into probabilities of harmful effects occurring.

Where there is this uncertainty, there may be a need to take regulatory action in advance of scientific evidence. An important consideration in designing such action will be the extent of environmental and human ill health risk aversion, and this will vary between different groups in society. One possible regulatory response is to base action on the safe minimum standards approach. This requires that no significant deterioration of the environment should occur unless the benefits associated with that deterioration heavily outweigh the costs of the deterioration.¹ In the case of existing substances, subjective judgements are often made about how to handle this uncertainty in terms of applying safety factors.

It is nevertheless important to try to translate the PEC/PNEC and PEC/PNOAEL ratios into expressions of probability that harmful effects will occur and, if possible, to evaluate the costs

¹ Annex 10 of the OECD Policy and Project Appraisal Manual sets some general basic principles of analysis for appraising regulatory control options under conditions of uncertainty about environmental damage and the effectiveness of the control outcome.

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attributable to those harmful effects. The extent to which this can be done will depend on the quality of the information that is available about the harmful effects of the substance, about the exposure-response relationships of exposed human groups or environmental targets, and whether there is a rational basis for assigning monetary values to the harmful effects. The types of conclusions that may be drawn will range from:

- 1) a qualitative statement about the nature of the risks to human health or the environment from the substance, and how the control measures are expected to reduce those risks; to
- 2) quantified estimates of risk probabilities and the amounts by which they are expected to be reduced by the control measures; to
- 3) monetary valuation of the risk estimates and the savings that would be expected, in terms of monetary valuation of the estimated statistical reduction of harm to people or the environment, by use of the control measures.

Costs to Industry and Consumers

The extent to which the economic effects can be quantified will depend on the information that is available about the ways the controls are likely to influence the markets for products affected by the controls on the substance.

The types of conclusions that may be drawn will range from:

- 1) a list of the qualitative advantages and disadvantages of the substance as currently used - and for the substance with the proposed control measures or for any substitute substance; to
- 2) quantitative estimates of the consequent changes in amounts of products demanded and supplied; to
- 3) the financial consequences of these changes in the market for the products in terms of changes in producer and consumer surpluses.

Table 1 shows a format and a checklist for compiling the consequences of control measures in comparison with the current use situation. All elements in the table will not be relevant for every case; nor is the list intended to be comprehensive. Consultation with producers and consumers is very desirable at this stage to check that all significant uses of the substance are taken into account and that all the consequences of control measures or substitutes have been considered.

In estimating costs to industry and consumers, the following decisions need to be made:

- 1) If the substance is a minor component of the costs of production of the product to be controlled, it will usually only be necessary to estimate changes in producer surplus;
- 2) If the substance is a major component of the costs of production of the product to be controlled, it will be necessary to estimate changes in both producer and consumer surplus.

Table 1 Example of systematic list of consequences of introducing controls

	Substances as currently used	Substance with proposed controls	Substitute substance
Advantages to users			
Disadvantages to users			
Advantages to producers			
Disadvantages to producers			
Advantages to other interests			
Disadvantages to other interests			
Other implications*			
- employment			
- trade			

*For example this might include general costs to business in terms of employment levels and competitiveness in local and international markets.

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Trading Off Risks and Benefits

Once the reductions in risks to human health and the environment from the control measures have been established, described and possibly valued, they can be compared with the consequences of those control measures for producers and consumers. A decision must be made on whether the overall changes that would result from the control measures are justified by the reduction in risks to people and the environment. The basis for this decision will range from a purely subjective comparison between qualitative statements of changes of risks and effects of control to a clear financial difference between monetary values of risk reduction and monetary estimates of net changes in producer and consumer surpluses.

Three generic examples of likely options can be identified along the spectrum from qualitative risk-benefit analysis to fully quantitative cost-benefit analysis. These also correspond to the similarly numbered points in Figure 2.

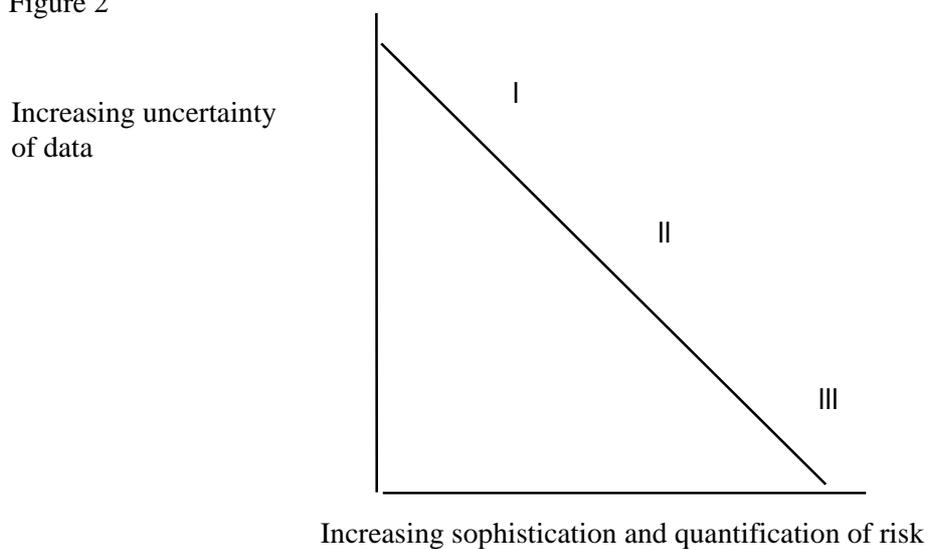
Example I

- If the risk quotient(s) is (are) based on data of poor quality, there may be little point in spending time, effort and money to obtain detailed economic data. A similar view might be taken if the risk quotient is much greater than 1, indicating with reasonable confidence a very high and clearly unacceptable risk, in which case all that may be needed is an order of magnitude assessment to check that the proposed control measures would not lead to any enormous disadvantages.
- If the above criteria apply, the appropriate form of risk benefit analysis is a qualitative risk benefit analysis (i.e. a systematic description but not quantification of risks and benefits). Lists of advantages and disadvantages should therefore be drawn up:
 - ◇ for the substance as currently used;
 - ◇ for the substance with the proposed control measures, and
 - ◇ for the proposed substitute substance.
- Table 1 (not reproduced) gives the main economic aspects that should be considered. In the table all the economic consequences of the proposed control measures and/or substitutes can be displayed for subsequent comparison with the environmental and human health consequences.
- A subjective judgement can then be made on whether the overall changes that would result from the proposed control measures, or use of a substitute substance, are acceptable in comparison with the reduction in risks (to human health and the environment) that would be achieved by those control measures, or substitute substance.

Example II

- This is a quantitative risk-benefit analysis which is likely to be applicable when more confidence can be put in the risk quotient(s) and when there is a finer difference between

Figure 2



This diagram illustrates how the degree of quantification that can be achieved in the comparison of risks and benefits depends on the availability and quality of data for both the risk assessment stage and the economic consequence stage. Situation I represents substances such as dioxins/benzene where both risk assessment and understanding of economic returns are limited. On the other hand, situation III represents substances such as lead where we have a thorough understanding of risk and economic returns from its use.

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- the quotient(s) for the substance under consideration and the value of 1, and/or between the quotient for the substance under consideration and its substitutes. Under these circumstances, there will be more justification in putting effort into the costing of the proposed control measures.
- So the information used here includes:
 - ◇ a risk quotient which is not a fully quantified assessment of risk and which therefore cannot easily or readily be converted into a monetary value;
 - ◇ a PNEC used in the risk quotient which gives target levels for control and from which their economic consequences can be assessed.
- The outcome for this exercise will be a statement of reduction in risk expressed in terms of a reduction in quotient and the statement of the net consequences of the control measure in terms of changes in the quantities demanded and supplied. If this were available across a range of options, a quantitative comparison could be made of the reduction of risk per loss of economic benefit for each.

Example III

- This is a full cost-benefit analysis, in which
 - ◇ there is a fully quantified, probabilistic statement of risk for ecological systems and human health, and/or
 - ◇ Example II leads to the need for judgements that are so fine and yet potentially of so great economic importance that it is worth investing the time, effort and finance in a complete cost-benefit analysis.
- Decisions will need to be made in terms of what economic values to apply to the risks.
- Valuation of economic advantages associated with the substance(s) under consideration will be carried out.
- The cost-benefit analysis can then be carried out with the substances under consideration or, in a comparative way, on it and its substitutes.

Summary Lessons from Examples:

- Example I is an essentially qualitative and subjective risk-benefit analysis that might be standardised at a later date in the light of experience.
- Example II is a more quantitative risk-benefit analysis that can be made more objective if applied in a comparative way. This is likely to be a preferred option in implementing Existing Substances Regulation 793/93.

- Example III is a fully quantitative cost-benefit analysis. In the context of Regulation 793/93 this is likely to be applied rarely and may be more common where there are concerns about human health, since here full valuation of health risks is more straightforward than the valuation of harm to the environment.

The Conclusions of Risk-Benefit Analysis

The sorts of conclusions that might be reached on the basis of risk-benefit analysis could be as follows:

- i) The proposed control measure/substitution does not lead to a significant loss of socio-economic welfare and its application is clearly justified by the reduction in risks achieved.
- ii) The proposed control measure/substitution results in a significant loss of socio-economic welfare, but which nevertheless appears reasonable in comparison with the likely reduction in risks to human health and/or the environment. Its application is considered desirable.
- iii) The proposed control measure/substitution results in a significant loss of socio-economic welfare which appears unreasonable in comparison with the likely reduction in risks to human health and the environment. More detailed analysis of advantages and disadvantages (possibly coupled with a refinement of the risk assessment) should be carried out; i.e. a more quantified assessment as per Example II and possibly III is needed in order to reach a conclusion.
- iv) The proposed control measure/substitution results in a significant loss of socio-economic welfare which is clearly unreasonable in comparison with the likely reduction in risks to human health and/or the environment. It should not be implemented.

A Cautionary Note

It may be tempting for risk-benefit practitioners to believe that they can provide the answer to regulatory control. This temptation should be resisted. Risk-benefit analysis is an art as much as a science. Often only conditional statements can be produced. The objective is to identify and reduce the uncertainty confronting the decision maker. There will often be room for debate about the measurement of particular parameters. In such circumstances one of the most important functions of risk-benefit analysis may be to raise the level of debate in international negotiations. It is not, however, itself a substitute for negotiation any more than it is a substitute for decision making.

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The Importance of Risk-Benefit Analysis in Risk Management Decision Making: Case Study of a Mercury Pollution Prevention Measure in Japan

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Introduction

In Japan, stringent countermeasures have been taken to regulate approximately ten toxic chemicals related to severe pollution incidents, such as Minamata Disease (MD) or Yokkaichi Asthma, which are referred to as traditional pollutants, while attention had not been paid to the regulation of toxic chemicals other than traditional pollutants, referred to as hazardous chemicals, until the beginning of the 1990s. During the 1990s, public concern about the toxicity of various hazardous chemicals has increased and the government has undertaken the regulation of hazardous chemicals. However, the government policy is not always based on comprehensive research or sound scientific and economic analysis, but is based upon topical issues or policies of the US EPA or international organizations such as WHO.

To be more specific, the policy of regulating hazardous chemicals places great stress on how to identify extremely toxic chemicals and strictly regulate them. The government seems to create policy on the basis of the hazardous characteristics of the chemical, irrespective of the risk posed by, or the benefits to society of, the chemical. This is, however, not an effective method for maximizing the risk reduction with limited resources, because the most hazardous chemical does not always pose the greatest risk and the risk posed by the most hazardous chemical cannot necessarily be easily reduced. In addition, considering that the chemicals to be regulated are changing from those which clearly cause damage to the ecosystem and injury to humans to a tremendous number of potentially toxic chemicals, our society is now faced with the urgent necessity of creating policy for regulating chemicals based firmly on scientific and economic analysis.

In creating policies addressing environmental issues, a risk-benefit analysis is important. Risk-benefit analysis is a variation of cost-benefit analysis and is often referred to as a type of cost-effectiveness analysis. This analytical tool allows policy makers to make decisions based on the trade-offs between the benefits and the risks.

We think the risk-benefit analysis is more useful in Japan than the cost-benefit analysis due to the following reasons:

- 1) Japanese society has had little experience in evaluating policy from socio-economic viewpoints, so data regarding willingness-to-pay (WTP) values for risk reduction are limited. The WTP for health risk reduction is usually estimated by using the data on wages and occupational risks (wage-risk method) or by using the contingent valuation (CV) survey. In Japan there have been few studies investigating differences in wages in the workplace and various risks, and some suggest that no relation has been observed between occupational risk and wage. On the other hand, there is no consensus, even among economists, on the reliability of the CV method to elicit WTP. Consequently, it is not possible to incorporate the economic benefits of risk reduction into the appraisal of environmental policies in Japan. In contrast, the risk-benefit analysis is more feasible, because it requires only the economic costs of reducing risks and the quantities of risk reduction.
- 2) The values of WTP for risk reduction estimated in other countries are not reliable enough for use as a basis to build a public consensus for Japan.
- 3) The environmental program, which aims to directly enhance human health, can contribute, to some extent, to reducing adverse effects on the ecosystem. Nevertheless, in many cases we measure the value of the benefits of the policy only from the perspective of reduction in human health risk, which in turn underestimates the benefits of the policy. Therefore, it is not appropriate to transfer the benefits of risk reduction of other sectors, such as medicine or occupation, into environmental protection. However, there is the problem that in our analysis we neglect the variations, among environmental policies, of the effects of ecological risk reduction even though the extent of the subordinate effects varies among environmental policies.
- 4) In economics a standard method of incorporating the ecological value of the control of toxic substances is to evaluate the economic benefits (people's WTPs) resulting from the reduction of adverse ecological effects and to add them to the economic benefits resulting from the reduction of adverse health effects, to yield the total economic benefits of the control. Environmental economists have accumulated a large number of estimates of people's WTPs for the protection of ecosystems or species, but pursuit of this course is not a good strategy for effective policy making. First, most of the estimates of the WTP for ecological protection have been obtained using the CV method, in which people's WTPs are elicited through hypothetical payments for a hypothetical supply of environmental goods (in this case, protection of ecosystems or species). There is no consensus, as mentioned above, even among economists, concerning the reliability of this method to elicit the true values of people's WTPs. Secondly, in many of these CV studies the "goods" to be evaluated are not well defined and the respondents in these surveys are required to put values to ambiguously defined goods and ambiguously defined increases in the amounts of such goods. This suggests that some scientific and objective measurement method of the ecosystem or species must be developed before assigning subjective values to it. It is too early at this stage to use the economists' estimates on WTP for ecological protection. Thirdly, the economic benefit is inherently a value of the present generation. However, the ecosystem should be protected mainly for future generations.

Intergenerational equity is not dealt with in the framework of net benefit maximization. Considering this limitation of cost-benefit analysis, if we could take the cost-efficiency into account when assessing environmental policies, the framework for minimizing costs to achieve given physical goals (which should be well defined) would be sufficient and much more practical.

The result of the risk-benefit analysis provides us with the value of a benefit-risk ratio (BRR), and policy makers can determine whether a policy is cost-effective by comparing the value of its BRR with those of other policies. Here, "other policies" include alternatives to the policy in question, as well as those already put into practice.

How to Measure Environmental Risks

In conducting a risk-benefit analysis, measurement of environmental risks is critically important. The environmental risks include human health risks, which are further classified into cancer risk and non-cancer risk, and ecological risk due to exposure to chemicals in the environment, mainly outside the workplace. Over the last two decades, methodology to measure cancer risk has been developed and revised mainly by regulatory agencies in the USA, and has also been accepted in international communities. Using this method, cancer risk is expressed in terms of the probability of an individual to develop any type of cancer associated with exposure to carcinogens. Thus, the calculated cancer risk is appropriate for use in the risk-benefit analysis.

Contrarily, a hazard quotient method is widely used to express non-cancer risk. With this method, a hazard quotient (HQ) for a single substance and a hazard index (HI) for multiple substances are used as risk indicators, and the chemical or mixture of chemicals is not considered to pose a risk to public health at exposures below the corresponding reference dose (HQ or HI less than 1). On the other hand, at exposures above the corresponding reference dose (HQ or HI exceeds 1) it is considered that there may be the potential for non-cancer toxic effects. However, this method cannot provide us with any information to estimate the extent of non-cancer risk based on the value of HQ in the range over 1, so it is not applicable for use in the risk-benefit analysis.

In addition, we must point out that the hazard quotient method does not allow quantitative comparison of cancer risk with non-cancer risk. Without comparing cancer risk with non-cancer risk, we cannot prioritize our options for regulating chemicals. Unfortunately, no well-accepted or established approach to this problem is currently available. As a possible solution, our research group has proposed that loss of life expectancy (LLE) should be used as a common metric of cancer risk and non-cancer risk. The LLE enables us to quantify and compare health risks, irrespective of whether they are cancer risks or non-cancer toxic risks. In this study, the LLE is used for evaluating different types of human risk.

Social Background of the Case Study

Since the mid 1960s, the Japanese government has introduced a succession of strict measures to reduce the toxic environmental effects of mercury following the occurrence of two outbreaks of MD due to industrial effluents from the acetaldehyde production processes carried out in Minamata (Kumamoto Prefecture) and in Niigata. In the beginning, these measures focused on the regulation of organic mercury, because organic mercury was believed to be dangerous while inorganic mercury was thought to be not so dangerous. However, the situation drastically changed in 1973 following reports of the possible

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occurrence of a third and fourth outbreak of MD in areas where the caustic soda production process, which was discharging not organic but inorganic mercury, was the only source of mercury. The reports led to panic reactions, such as consumers' nation-wide boycott of fish for fear of mercury poisoning. In the same year, the government enacted the policy that the mercury electrode process used in caustic soda production should be replaced by non-mercury processes by the end of fiscal 1977. At that time, 95% of caustic soda in Japan was produced using the mercury electrode process. Finally, by September 1986, the caustic soda plants using the mercury electrode process were completely replaced by non-mercury plants.

The occurrence of the fourth outbreak of Minamata Disease was suspected to originate from the Tokuyama district facing Tokuyama Bay, located at the northwest of the Seto Inland Sea. There were two factories with caustic soda production plants in Tokuyama which used the mercury electrode process to produce about one-tenth of the total caustic soda production in Japan and discharged their effluents into the bay. According to a large-scale survey of mercury pollution, it was ascertained that fish from Tokuyama Bay was contaminated with mercury, and as a result Tokuyama Bay was closed to fishing from 1976 to 1983, though it was partially reopened in 1979. The epidemiological survey suggested that relationships between fish consumption and mercury content in hair, and between fish consumption and age-adjusted incidence of paresthesia, were observed although no resident was officially recognized as having Minamata Disease [Nakanishi and Ukita (1989)].

This study attempts a risk-benefit analysis of the government decision to prohibit the mercury electrode process in caustic soda production in 1973. In this study, the reduction in human health risk due to the prohibition of the mercury process and the costs incurred by this decision are evaluated, from which the BRR value of this decision is estimated. All parameters needed for risk estimation are obtained by simulating "Tokuyama Bay" (Nakanishi, 1997).

Risk Estimation in the Case Study

Assumptions Regarding Caustic Soda (NaOH) Production

In this section, the incremental human health risk that a continuance in use of the mercury electrode method would pose is estimated. In estimating the incremental risk, the following assumptions are made. A total of four million tonnes of caustic soda per year is produced in chloralkali plants located in ten areas throughout Japan. Each plant is roughly identical with respect to production capacity and process employed. In other words, 400 thousand tonnes of caustic soda is produced annually in each area. All mercury discharged into the environment in one area ultimately flows into a nearby bay. A total of ten bays throughout Japan are considered. The geographical and biological conditions of each of the ten bays are represented by that of Tokuyama Bay in this study.

Six grams of mercury is consumed (lost) per tonne of caustic soda produced; 20% of the mercury consumed is discharged into the environment, and thus 0.48 tonnes of mercury is discharged into each bay annually. Most of the 80% of the mercury that is consumed is retained in process plants and some is retained in wastes such as brine mud. Assumptions made for this study are summarized in Table 1, along with the data from Tokuyama Bay in the latter 1960s.

Estimation of Mercury Level in Sediment from the Bay

A weighted average mercury level in the sediment (mg/kg of sediment, dry basis) is estimated using the equation derived from the relationship between the level of heavy metals in sediment and the amount of the heavy metals discharged into the bay which Nishimura and Kumagai (1974) formulated. An estimated weighted average mercury sediment level at 0.53 mg/kg is obtained as shown in Table 1.

Estimation of Mercury Levels in Fish

The mercury level in fish, gilthead and sardine, respectively, is estimated using equations derived from the results reported by Nakanishi et al. (1989) regarding the relationship between mercury level in fish and the sediment from Tokuyama Bay. Gilthead is representative of the fish species with a high mercury level and sardine is representative of that with a low mercury level. The calculated average mercury levels are 0.24 mg/kg for gilthead and 0.06 mg/kg for sardine, when the average mercury level in sediment is 0.53 mg/kg. These results are shown in Table 1. Furthermore, it is assumed that 80% of the mercury in fish is methylmercury.

Methylmercury Intake by Residents

The residents of the study area are classified into three groups in terms of their fish consumption habits. The first group are heavy fish eaters, numbering 300 in each area. This number is determined on the basis of about 10% of the population belonging to families in fish related business such as fishermen, fish mongers and sushi-cooks in the Tokuyama district. It is assumed that people in this group consume 320 grams of fish caught from the bay per day [Futatsuka (1979)]. People in the second group consume only fish caught in Tokuyama Bay and the number of the second group, determined by the amount of fish caught in Tokuyama Bay, is assumed to be 133,000 in each area. Furthermore, it is assumed concerning people in the second group that individual variability regarding fish consumption follows a log-normal distribution, with the geometric mean of 97 grams per day [Ministry of Health and Welfare (1997)] and the geometric standard deviation of 0.176 [Shirai (1988)]. The third group includes people who don't eat any fish from the bay. Accordingly, assuming that people eat an equal amount of giltheads and sardines, the calculated daily methylmercury intake for individuals in the three groups is shown in Table 2.

Probability of Methylmercury Poisoning

Next, to numerically represent the human health effects caused by exposure to methylmercury, the relationship between the methylmercury daily intake and the probability of paresthesia reported by Nordberg and Strangert (1976) is applied to different groups of the total population. The possible increase in cases of paresthesia due to increased intake of methylmercury via fish consumption is calculated. Next, to estimate incidence of paresthesia per year, information concerning the replacement ratio of residents is necessary. Assuming that the ratio of replacement is 100% every year, incidence of paresthesia per year is calculated to be 40.6 cases per year, which is referred to as the most conservative estimate. And assuming that the ratio of replacement is 10% every year, incidence of paresthesia is calculated to be 4.1 cases per year, which is referred to as a more probable estimate.

Estimation of LLE

The amount of loss of life expectancy (LLE) which would have been avoided by the prohibition of the mercury electrode process is estimated. To calculate the LLE, we assume that the development of paresthesia at a certain age would increase the annual death rate from that of the control population at that age by 27.17% for males and 19.71% for females uniformly, irrespective of age. This is based on the standardised mortality ratio (SMR) values for MD patients in Minamata estimated in the epidemiological study by Kinjo et al. (1991). In this study, the SMR values are used to estimate the increase in death ratio due to MD for all age classes, because the data concerning the increase in death rate by age are not available to us.

Using the above values of mortality due to paresthesia, the population by age in 1990 and the life-table of Japan in 1990, we obtained the value of 2.24 years as LLE for men and the value of 1.49 years for women. The average of these two values weighted by the populations of both sexes is 1.85 years. This means the LLE induced by one case of paresthesia. Assuming the estimation of 40.6 and 4.1 cases of paresthesia avoided by the prohibition of the mercury process per year, the avoided LLE would be 75.1 and 7.5 years per annum, respectively.

Evaluation of Benefits*Estimation of Expenditures*

In this section, the reduction in the benefit occurring from prohibition of the mercury electrode process is evaluated. If caustic soda produced by the mercury electrode process and non-mercury processes is identical in terms of quality of the products and the running costs of the process, the reduction in benefit occurring from the prohibition is represented by the costs incurred from the replacement of plant processes, from the mercury electrode process to non-mercury processes. Here, the differences in quality and running costs between the three processes, the mercury electrode, the diaphragm and the ion-exchange membrane, are regarded to be negligible.

According to a survey by the Japan Soda Industry Association, the total expenditures incurred in replacing the mercury electrode process by non-mercury processes amounted to 334.2 billion yen from fiscal 1973 through fiscal 1988. Of this, 287.3 billion yen was spent to change the mercury electrode process to the diaphragm process or the ion-exchange membrane process and 46.7 billion yen was spent for the second replacement, from the diaphragm process to the ion-exchange membrane process [Japan Soda Industry Association (1982)].

The yearly expenditures for replacement are estimated based on data published by the Japan Soda Industry Association. The expenditures estimated for each year from 1973 to 1988 are adjusted in terms of 1989 yen value and are shown in column B in Table 4. Annual worth of the stream of the expenditures from 1973 to 1988 is calculated to be 19.8 billion yen, assuming that social discount rate is 5% and the duration of the effects of the whole stream of the expenditures is 33 years. This is consistent with the assumption about the life-span of plants given below.

Estimation of Valid Reduction in Mercury Discharged

First, the amount of caustic soda produced using the new processes which replaced the mercury electrode process is estimated for each year. Next, the reduction in mercury discharged into the environment resulting from the process change for each year is estimated assuming a reduction of 1.2 grams for every tonne of caustic soda produced by the new processes. The figures for the consecutive years from 1973 to 1986 are shown in column C in Table 4. Moreover, it is assumed that the reduction in mercury discharged brought about by replacement of the mercury process is valid for twenty years, corresponding to the life-span of the newly built caustic soda production plants. Then, the sum of the valid reductions in mercury discharged for the respective years is calculated and shown in column D. Regarding the quality of the environment as a kind of resource, the amount of mercury discharged is treated as if it were an expenditure. That is to say, the annual worth of the sum of the valid reduction in mercury discharged from 1973 to 2005 is calculated under the social discount rate of 5% and the period of 33 years. The figure thus calculated is 2220 kg/year.

The annual worth of expenditures is divided by the annual worth of the valid reduction in mercury discharged. This is calculated to be about 8920 yen per one gram/year of valid reduction in mercury discharged, which roughly equals \$90 per gram per year.

Estimation of the BRR Value

As shown in Table 1, the replacement of the mercury electrode process by the non-mercury processes brought about 4.8 tonnes of valid reduction in mercury discharged per year. For this purpose, an expenditure of 42.8 billion yen, 8920 yen per gram multiplied by 4.8 tonnes, was incurred. And the reduction in human health risk of 75.1 or 7.5 life-years was brought about. In conclusion, the BRR value of the prohibition of the mercury electrode process is about 570 million yen per life-year for the most conservative risk estimate and 5700 million yen per life-year for the more probable risk estimate, calculated as 42.8 billion yen divided by 75.1 and 7.5 life-year respectively.

Evaluation of the Policy

Let us compare the BRR value of the policy in this study with those of other policies. Previously, we estimated the BRR values for two cancer death reducing policies and one pesticide regulation; the former consists of the policy of replacement of chlorination by ozonation in the process of water purification [Nakanishi (1989)] and the policy of reduction of benzene content in gasoline from the current level to 1% in volume [Nakanishi (1995)], and the pesticide case concerns replacement of chlordane by chlorpyrifos [Oka et al. (1997)]. The estimated BRR ranges from 300 million to 570 million yen per cancer death reduced. According to the results of Gamo et al. (1996), that the magnitude of risk of a cancer death is identical to that of the risk of 12.6 years in terms of LLE, the BRR values are calculated to be 24-45 million yen per life-year saved for the above three policies.

Tengs et al. (1995) analysed the cost per year of life saved for 587 life-saving interventions. According to their results, it ranges up to more than 10 billion dollars per year of life saved. Among 587 life-saving interventions, the median cost per life-year saved for toxin control interventions in the area of environmental protection issues is \$4.2 million. The BRR value with the policy in this study is much higher than with the three policies formerly studied by us, and even a little higher for the most

conservative estimate and much higher for the more probable estimate than the median values for cases in the United States studied by Tengs et al.

Discussion

This analysis indicates that the government decision on the prohibition of the mercury electrode process was far from cost-effective. However, the ion-exchange membrane process developed to replace the mercury electrode process is excellent, not only in terms of reduced mercury emission but also in terms of energy conservation. In this sense, the direction of the government policy was not wrong. If the replacement of the mercury process had been implemented when industry renewed existing plants, the value of BRR would have been markedly decreased.

It was due to panic reactions that the government determined the policy to prohibit the mercury electrode process. Panic reactions were aggravated by the disclosure of mercury pollution data kept secret until then. In addition, since the government had often advocated the zero-risk principle, it was forced to take extreme measures. Although the government's decision seems radical, in reality the long-term negligence by the government and the industry in not taking countermeasures against mercury pollution forced the government to take this extreme measure.

To prevent development of such an extreme policy, the government must abandon the zero-risk position and provide information regarding pollution to the public. In the context, risk communication is a key for Japanese society, in other words, for both the government and the public.

The present study has been conducted by a research group which consists mainly of engineers, ecologists and economists based at universities which have been financially supported by the Japan Science and Technology Corporation. The results were published in a leading monthly general-interest magazine in a series of twenty issues, from 1992 to 1994, and were later collected in a book by Junko Nakanishi in 1995. Although the study was conducted for personal reasons, its publication greatly influenced the research related to environmental policies and the directions of development of government environmental policies. Since then, risk assessment and risk management have become major topics to be addressed by regulatory agencies and ministries of the government.

This study also indicated that environmental protection policies should be examined from the perspective of cost-effectiveness. Since discussion on policies related to MD was long considered taboo, these policies were not examined from the standpoint of economic efficiency. Such hesitation lasted partly due to sympathy for the approximately three thousand recognized MD patients and approximately ten thousand people also suspected to be affected with MD, but mainly because the belief that nothing can take the place of a human life prevails in Japan.

This study triggered the regulation of airborne hazardous chemicals. In particular, it provided the scientific and economic grounds for establishing an ambient air quality criterion for benzene. Our study illustrated that the ambient criterion of $4 \mu\text{g}/\text{m}^3$ for benzene can be attained by reducing the benzene content in gasoline from the current level to 1% in volume. The BRR with this policy is 45 million yen per life-year saved, which equals roughly US\$ 450,000. This BRR value is within the range of those of several policies currently implemented, and it is much lower than the BRR value for the prohibition of the mercury electrode method in the caustic soda production process. In reality, the ambient air quality criterion for benzene was established as $3 \mu\text{g}/\text{m}^3$ and promulgated by the government in 1996.

The noteworthy achievement of this study was that the risk due to methylmercury exposure, a non-cancer risk, was estimated. In implementing rational policy based on sound scientific or economic analysis, it will be an urgent task to evaluate human health risks due to chemicals for which a no-effect threshold can be determined. These chemicals include non-carcinogens and carcinogens without mutagenicity, which are both treated here as non-carcinogens. Generally, regulatory organisations in many countries set ambient criteria of non-carcinogens so that exposures to them would be below their corresponding reference dose. That is to say, the principle for non-carcinogens is zero-risk. The reference doses are generally not as low for fatal diseases, while the no-effect level for symptoms or phenomena such as reduction in total lymphocyte counts caused by elevated dioxin body burden is reportedly a very low value. If the zero-risk principle is applied to all non-carcinogenic adverse effects due to chemical exposure, the regulation, whether legislative or realistic, may be less cost-effective. To prevent such confusion, we must conduct more studies to develop methods to evaluate non-cancer risks and to determine the weights of different types of risk.

While I believe that the study reported here greatly contributed to the development of risk-benefit analysis, much remains to be studied. The critical shortcoming of this study is that there was no opportunity for fishermen and residents to take part in the analysis.

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Table 1. Mercury Data

	Assumptions in this study			Tokuyama Bay in the 1960s
	nation	one bay	baseline	
NaOH production (1,000 tonnes)	4,000	400		400
Hg discharged (tonnes/year)	4.8	0.48	0	3.62
Hg in sediment (mg/kg)		0.53	0.03	4
Hg in gilthead (mg/kg)		0.24	0.2	0.6
Hg in sardine (mg/kg)		0.06	0.05	0.13

Hg = mercury

Table 2. Daily Intake of Methylmercury

Group	Consumption of fish from the bay (g/day)	Background MeHg intake (mg/day)	Increment of MeHg intake (mg/day)
1	320	32	8.7
2	97 (mean)	9.7	2
3	0	9.7	0

MeHg = methylmercury

Table 3. Conservative Estimate of Human Health Risk throughout Japan

	Group 1	Group 2	Total
Population (thousand)	3	1,330	1,333
Probability of paresthesia	6.4×10^{-3}	2.9×10^{-5}	
Paresthesia risk (cases/year)	1.92	38.7	40.6
LLE (life-year)	3.6	71.6	75.2

Table 4. Costs and Effects due to Replacement of the Mercury Electrode Process

A	B	C	D
Year	Expenditure in 1989 yen (billion)	Reduction in mercury discharged (kg)	Valid reduction in mercury discharged (kg/year)
1973	68.66	0	0
1974	57.44	790	790
1975	55.59	742	1,532
1976	51.83	304	1,836
1977	51.18	48	1,884
1978	1.24	43	1,928
1979	1.19	59	1,986
1980	1.12	15	2,002
1981	1.12	283	2,285
1982	4.82	48	2,333
1983	15.15	125	2,458
1984	15.60	403	2,861
1985	23.40	518	3,379
1986	20.09	134	3,514
1987	14.33	0	3,514
1988	1.60	0	3,514
1989	0	0	3,514
1990	0	0	3,514
1991	0	0	3,514
1992	0	0	3,514
1993	0	0	3,514
1994	0	0	2,724
1995	0	0	1,982
1996	0	0	1,677
1997	0	0	1,629
1998	0	0	1,586
1999	0	0	1,527
2000	0	0	1,512
2001	0	0	1,229
2002	0	0	1,181
2003	0	0	1,056
2004	0	0	653
2005	0	0	134
Annual worth	19.8	137	2,216

Economic Analyses In Support Of Environmental Standards Development - Experience In Ontario

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(Views and opinions expressed in this paper are those of the authors and do not necessarily represent the policies of the Ministry of Environment or the Ontario Government)

Introduction

The Ontario Ministry of the Environment (MOE) is empowered to set ambient quality standards for all environmental media and pollutant release standards for most public and privately owned emitters and sources.¹ The province, through the Ministry, also administers national statutes, regulations and standards.

Economic analyses have been implemented to support the development of environmental initiatives in Ontario for over two decades. However, retrospective evaluations of existing programs and policies are seldom carried out. The Ministry regularly employs risk assessment, risk management, public consultation, atmospheric transport models, water and atmospheric dispersion modelling and forecasting together with economic assessments to set ambient quality standards as well as effluent or emission limits for major industrial point sources.

Most economic assessments have emphasized the costs of proposed regulatory programs and their economic implications for economic sectors and individual firms (eg. Ontario Ministry of the Environment, March 1987; Donnan and Salamon, Nov. 1988; VHB Research and Consulting, July 1990, and Donnan *et al.*, Nov. 1990). Assessments of cost implications and the benefits of regulatory programs on individuals or firms can be invoked by stakeholders under Procedure F-14 of the Ministry Manual of Procedures and Guidelines ("Economic Analyses of Control Documents or Private Sector and Municipal Projects"). Since 1995, the Ontario government has required that evaluations of both benefits and costs be conducted for all new regulations that are submitted to cabinet.²

Economic assessments are carried out by staff in the Economic Services Branch of the Ministry on a consultancy basis with other Branches in the Ministry.³ Most of this work is carried out in-house but outside consultants are sometimes employed. Economic assessments are normally interdisciplinary exercises involving engineers, biologists, chemists, hydro-geologists and atmospheric scientists.

This paper concerns economic analyses in support of developing ambient quality standards. Assessments have been applied most recently in the development of ambient quality standards in Ontario for lead, arsenic, total reduced sulphur compounds and tritium in drinking water.⁴ The authors also have

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developed an interdisciplinary framework for evaluating the economic implications of proposed harmonized Canada-wide standards for selected contaminants under the auspices of the Canadian Council of Ministers of the Environment (CCME).⁵

After presenting a brief outline of procedures by which ambient quality standards are established in Ontario, we review the methods used for socio-economic assessments in support of standard-setting in Ontario. We then summarize the economic assessments employed in the development of standards and criteria for lead in a multi-media context (soil, drinking water and air). Conclusions about the role and usefulness of economic assessments in standards development are presented along with suggestions as to how such assessment might be improved.

Setting Ambient Quality Standards in Ontario

The Ministry of the Environment sets environmental quality standards for all media including air, drinking water, surface water, soil, sediments and certain biota. While the terms standards, guidelines and objectives tend to be used interchangeably, under Ontario statutes, the definitions are legally quite distinct. "Standards" refer to legally enforceable, mandatory requirements specified in a regulation that apply to all parties which emit the regulated contaminants. The only standards that have been codified in Ontario are half-hour ambient air concentration standards under Ontario Regulation 346. "Objectives," "guidelines" and "criteria," such as those specified in Ontario Regulation 337 (ambient air quality concentrations), in the *Ontario Drinking Water Objectives* (Ontario Ministry of the Environment, 1994) or in *Guidelines for Decommissioning and Clean-up of Sites in Ontario* (Ontario, 1994) are not legally enforceable unless incorporated into a legal instrument.⁶ In this paper, the term standard is used generically to refer to both mandatory standards and non-enforceable guidelines, objectives and criteria which are established for specific contaminants in each environmental medium.

The Ministry employs risk assessments as the initial basis for setting ambient quality standards.⁷ Quantitative information and data on the human health effects and other hazards associated with an environmental stressor are derived from risk assessments together with dose-response functions and sources and levels of exposure for the general population and sensitive sub-populations.

In the past, standards were developed and promulgated for each environmental medium separately with little or no consideration of cross-media transfers. More recent standard setting efforts develop standards in a multi-media context because people frequently are exposed to the same contaminant via several different pathways. Management of total exposure and body burdens of contaminants requires that standards be established for each potential source in concert.

Standards are established primarily to protect human health but the protection of more sensitive vegetation or aquatic organisms may be the key motivation for some substances. Approximately 900 ambient quality standards, guidelines and criteria have been established in Ontario. These standards include over 350 separate chemical compounds in air, water, soil, and sediments. Standards are set so as to achieve prespecified levels of human health risk ("risk-based") or so that there are no known adverse health or environmental effects ("effects-based").⁸

Ambient quality standards may also be based on concentration levels which can be achieved with available abatement or pollution prevention technologies. These are known as "technology-based" standards. This approach is more commonly applied in setting pollution release (effluent or emissions)

limits but are used occasionally to establish enforceable air quality standards at point of impingement for specific plants or industrial sectors. Environmental agencies have devised a variety of different criteria and definitions for technology-based standards including “best available technology” (BAT) and “maximal achievable control technology” (MACT). Cost analyses and financial impact assessments (sometimes called “economic achievability”) are frequently considered when developing technology-based standards.

Standards set by other agencies in other jurisdictions, including the United States Environmental Protection Agency (US EPA), are usually consulted prior to recommending an Ontario standard.

For example, provincial water quality objectives are generally effects-based standards in that they define a limit below which adverse effects are not expected to occur for the most sensitive species. While not legally binding on firms, provincial water quality objectives are used to set conditions in Certificates of Approval which are legally binding.⁹ Questions about the technical or financial ability of a particular source to comply with a specific water quality objective at the point of discharge may be considered on a case-by-case basis when a Certificate of Approval (permit) application is reviewed. Certificates of Approval can be issued with various conditions including emission or discharge limits. However, these conditions, as well as the refusal by the Ministry to issue an approval, may be appealed to the Ontario Environmental Appeal Board.

On the other hand, mandatory air quality standards at point of impingement under Ontario Regulation 346 (also called “POI” standards) define legally enforceable regulatory limits which apply to all regulated sources at all times. Because these standards are mandatory by regulation and are non-appealable, government policy requires that these proposed standards be evaluated to determine whether they are technically achievable and that the societal costs associated with meeting a standard are reasonably commensurate with the anticipated benefits. POI values based on risk assessment constitute the “point of departure” for the Ontario standard-setting process. Socio-economic analysis becomes an integral component of this process wherein trade-offs among levels of risk protection, costs and other beneficial (or adverse) consequences are determined and made explicit. Risk assessment results are integrated with information from engineering, financial and social-science assessments in order to derive a standard which is judged environmentally justified, technically feasible, financially sustainable and fair to all regulated parties.

A critical, but sometimes overlooked, component of any standard setting process is meaningful public participation to ensure that standards being recommended are acceptable to those who bear the costs as well as to those who enjoy the benefits. To facilitate public participation in Ontario, results of risk analyses, relevant data, assumptions, economic methods, decision-making criteria and uncertainties associated with the development of a standard are summarized along with recommendations in a public “Rationale Document.” Where a contaminant is particularly controversial or the economic implications are severe, stakeholders may be involved at early stages when risk analyses and economic assessments are carried out. In recent standard-setting exercises, implementation plans have been developed in addition to recommended standards. Normally, regulated parties and non-government environmental advocacy groups (referred to as NGOs) would be involved at this stage.

Public participation in the development of standards and other regulatory initiatives is facilitated in Ontario through a public review and comment period (at least 30 days) on an electronic registry established under the provincial *Environmental Bill of Rights Act, 1993*. Between 1993 and

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1995, public review, comment and advice on standards were also provided by the Advisory Committee on Environmental Standards (ACES), an independent advisory body which reported directly to the Minister.¹⁰

Typically, only stakeholders who are directly affected by particular standards provide comment during the public review period. These stakeholders include regulated parties, individuals who live near prominent sources of the contaminant of concern and various environmental advocacy groups. In some instances other provincial ministries submit comments from their particular perspectives (eg. Agriculture and Food, Industrial Development and Trade).

The socio-economic assessments that were carried out in support of the development of multimedia standards and guidelines for lead are illustrative of the application of socio-economic evaluations to standards development in Ontario, and of the influence that the results of these assessments have on the recommended standard.

Economic Assessments in Support of Standard Setting - Objectives and Methods

The key questions asked by government managers, elected officials and other stakeholders about the economic effects of proposed environmental regulations and standards nearly always concern compliance costs: How much does the initiative cost? Who will incur these costs? Will these costs impose undue financial hardships? Will the proposed regulation or standard precipitate strong objections to the government from regulated parties? Will any firms be forced to close plants and will there be any job losses? How much can a company afford to implement compliance with standards or requirements? More recently, and more frequently, other government agencies are asking about the potential benefits of proposed standards and requirements. However, the chief concern invariably revolves around costs, their distribution and their implications.

Economic methods employed to address these concerns include derivation of least-cost abatement cost functions, determination of cost-effectiveness, benefit-cost assessments, financial impact analyses of direct and indirect compliance costs on firms and industries, determination of the effects on community incomes and employment and the evaluation of distributional consequences among communities, ethnic groups (aboriginal people) and income classes. Analyses of proposed standards typically employ microeconomic tools, principles and perspectives. Macroeconomic assessments generally are not warranted because the magnitudes of potential costs in these cases are often too small to affect macroeconomic models. Moreover, it is not always possible, or necessary, to apply the full range of available economic analysis methods and techniques described in this section to each contaminant.

The distribution of costs and benefits among communities and social groups is often of concern to government decision-makers as well as many stakeholders. Determination of the incidence of the economic effects of proposed standards and other environmental policies is, therefore, an essential feature of economic assessments.

Consideration of more than one potential standard is important for at least three reasons. First, costs of the initial proposed standard may be intolerably high and provoke so much protest that agencies will be forced to formulate and consider less costly levels. Second, derivation and evaluation of alternative standards are invariably demanded by stakeholders, some of whom want more stringent

requirements while others want less. Third, presenting stakeholders and decision-makers with the incremental costs, and benefits, of a range of potential standards will invariably result in more informed decisions.

Where possible, we try to evaluate at least three sets of standards. For example, where prior risk analysis has produced a recommended standard, two additional standards are defined systematically for comparison: one that is more stringent and the other less stringent. Alternatively, additional standards for comparative purposes may be defined in terms of control technologies. For example, one polar case would be to determine the ambient quality concentrations that could be achieved by implementing the maximum degree of contaminant releases reductions that are technically achievable (also known as the Lowest Achievable Emission Rate or LAER). As noted, technology-based concepts such as Best Available Technology, Economically Achievable are sometimes employed to derive potential standards. However, these approaches do not consider environmental effects and “best available technologies” change over time. Therefore, technology-based standards should always be compared with the results of risk assessments in order to ensure that health and the environment are protected.

Cost estimation necessitates assumptions about specific technologies to reduce, control or manage contaminant release and/or exposure. To the extent possible, we try to postulate at least three technology and/or risk management options in order to determine a range of costs and to determine which options are more cost-effective.

Cost analyses include derivation of least-cost abatement cost functions, determination of least-cost configurations of abatement to achieve specified standards and assessment of the financial and competitive effects of the compliance costs. They further provide the information that is normally requested by government and stakeholders. Results of these analyses can also help to anticipate complaints from regulated parties and to respond to assertions about adverse economic effects by these same parties. However, cost assessments alone do not provide clear guidance or indications of what standard should be adopted.

Benefit-cost analysis that is suitably modified for application to environmental issues is our preferred approach to generate information that can help choose a standard (Donnan, 1996). Ideally, standards should be set so that the value of benefits are commensurate with costs. However, there is seldom sufficient information, resources or available time to produce a comprehensive and thorough benefit-cost analysis that lead to an unequivocal recommendation for a standard. Information and data on the quantities and value of potential benefits is particularly difficult to generate and uncertainties regarding various bio-physical relationships abound. Nevertheless, the results have been shown to be useful in making informed choices, as will be illustrated in the case study below.

Uncertainties associated with health and environmental dose-response relationships, calculated risk levels, benefits and costs estimates are examined by estimating low, medium (or “best estimates”) and high values for uncertain variables. Sensitivity analyses can show which uncertain variables have the greatest effects on final results. Monte Carlo techniques to generate probability distributions of uncertain benefit or damage estimates have been applied to other issues and initiatives (Victor and Burrell, 1983) but not, as yet, to the standard-setting cases identified or discussed in this paper.

In the context of environmental policy development with its emphasis on natural science input, the scope, credibility and usefulness of economic analyses are too often diminished because they are applied as an “add-on” evaluation step near the end of the policy development process. However, in

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recent programs and initiatives such as the case study discussed in this paper, economic analysts have been involved early enough in the process to allow sufficient time to complete the economic assessments in a credible manner.

Other challenges and issues associated with economic assessments in support of environmental standard setting and presenting results of such analyses for use in public consultation and decision-making include: 1) identification, quantification and valuation of the public benefits associated with proposed standards, 2) the integration of risk assessment and other bio-physical information and data with economic information and data, and 3) presenting the results of uncertainty analyses in an accessible manner to lay persons and decision-makers. These issues will be discussed as appropriate in subsequent sections of the paper.

Case Study: Development of Standards for Lead in Air, Drinking Water and Soil

The process by which standards for lead in air, drinking water and soil were recommended and finally promulgated involved the publication of two reports in support of public consultation, a 90-day public review period conducted by ACES, recommendations from ACES that arise from the review and approval by the Minister of specific standards. The first of the two reports was a detailed toxicology and risk assessment compiled and released in the *Scientific Criteria Document for Multimedia Environmental Standards Development - Lead* (Ontario Ministry of Environment and Energy, March 1994). The socio-economic assessment was included in the second report, a rationale document that recommended specific standards (Ontario Ministry of Environment and Energy, Dec. 1994a).

Although it was released in March 1994, the scientific criteria document had been completed over a period of 3 years prior to 1993 and was used in preparation of the rationale report. A co-author of this paper (Bailey) chaired the Ministry staff committee that authored the rationale document (Ontario Ministry of Environment and Energy, December 1994a). The chairperson and one other staff member worked the equivalent of 1 person-year on the rationale document during 1993 and 1994. The economic assessment work included in the rationale document was carried out by the staff economist and a research assistant. Another co-author of this report (Donnan) supervised one economist who carried out the socio-economic analysis. In total, approximately 0.5 person-year of effort was devoted to the socio-economic analysis over a 12-month period.

Standards that were proposed are summarized in Table 1, along with existing standards and guidelines for comparison.

Table 1

Recommended Multimedia Standards and Guidelines for Lead, Ontario

Type of Standard/Guideline	Existing Standards	Proposed Standards
Soil - Decommissioning Guidelines residential/parkland agricultural industrial/commercial	500 ppm 500 ppm 1000 ppm	200 ppm 200 ppm 1000 ppm
Ontario Drinking Water Objective	10 ppb	10 ppb
Air - Ambient Air Quality Criteria (Reg. 337) 30 day AAQC 24 hour AAQC Air - Point of Impingement Standard (Reg. 346) ½ hour POI.	3 µg/m ³ 5 µg/m ³ 10 µg/m ³	0.7 µg/m ³ 2 µg/m ³ 6 µg/m ³
ppm = parts per million ppb = parts per billion µg/m ³ = micro-grams per cubic meter Source: Ontario Ministry of the Environment and Energy, Dec. 1994a.		

Risk Characterization

Lead is a toxic heavy metal which has had widespread historical use and is found in such products as solder used in cans and plumbing, gasoline, paints and certain pesticides. Although lead exposure to the Ontario population has declined over the past several decades, due largely to the phase-out of leaded gasoline throughout Canada, several recent studies were noted in the Scientific Criteria Document to suggest that adverse health effects can occur at levels of exposure previously considered safe (Ontario Ministry of Environment and Energy, March 1994).

Exposure to lead can adversely affect human reproductive, renal, cardio-vascular, blood forming and developing central nervous systems. Young children (aged six months to 4 years) are considered to be at the highest risk of lead exposure because, they have the highest daily lead intake relative to body weight and they absorb lead more efficiently than adults. Blood lead levels are measured in micro-grams per deca-litre (µg/dL) and indicate degree of exposure. Studies of blood lead

levels in children cited in the Scientific Criteria Document have suggested that behavioural abnormalities and learning deficits can occur at levels as low as 10 µg/dL - levels which hitherto had been regarded as safe (Ontario Ministry of Environment and Energy, March 1994). Agencies in many jurisdictions, including the MOE, recognize that a blood lead level of 10 µg/dL or higher in children is a cause for concern. As many as 18,000 children in Ontario could have blood lead levels greater than 10 µg/dL.¹¹

The focus of the standard-setting exercise was human health effects and the pathways by which people are exposed to lead. The effects of lead on terrestrial biota were also examined as part of this standards-setting exercise. Based on a review of the literature, it was concluded that human health effects are the most sensitive end-point for developing air and soil standards. Standards protective of aquatic life and surface waters are developed through a different process and were not considered in this exercise. Although the US EPA has identified the potential carcinogenic effects of lead as a concern, this end-point was not considered because of uncertainties and knowledge gaps with respect to the dose-response relationship. Consequently, children under the age of four years were chosen as the most sensitive population while learning and behavioral deficits were defined as the critical endpoints. Moreover, standards protective of young children are presumed to protect adults.

Because lead can enter a human through a variety of pathways, a multi-media standard setting approach was adopted whereby the total Intake of Concern for a population (IOC_{pop}) was defined as the measure of exposure. The IOC_{pop} is analogous to a tolerable daily intake (TDI) for individuals. A target IOC_{pop} was set to ensure that the vast majority of children below four years would have blood lead levels below 10 µg/dL. The IOC_{pop} of 1.85 µg/kg/day was derived from the relationship between exposure to lead (intake) and blood lead levels in children. This standard also incorporates a safety/uncertainty factor of 2 in order to account for variability in the population and uncertainty. Because of the extensive body of human data available, the overall level of uncertainty was believed to be low.

The IOC_{pop} was allocated among the three media on the basis of an exposure assessment for children in Ontario which indicates that approximately 24% of exposure derives from food; 64% comes from soil, 11% results from drinking water and less than 1% comes from direct inhalation (Ontario Ministry of Environment and Energy, Dec. 1994a).

Key sources of lead exposure to people and wildlife included lead-based house paints, lead in food cans, lead-glazed ceramics, pewter dishes, crystal, hobbyist materials, spent shot and fishing sinkers. Although none of these sources were covered by the standards proposed in the rationale document, a guidance manual for health professionals was developed as part of this initiative to provide direction on measures which could be taken to minimize exposure from all potential routes of exposure to lead.

As noted in the rationale document (Ministry of the Environment and Energy, Dec. 1994a), "While the desirable health-based limits define the starting point for the derivation of revised standards and guidelines, other factors such as technical feasibility, background levels in Ontario and the costs associated with meeting such criteria were also examined. The resulting standard or guideline attempts to strike a balance between the desirable health-based limits and these other factors."

It is desirable for risk assessments and economic assessments be carried out concurrently to facilitate dialogue and feedback concerning data requirements. In this case, the risk assessment work had been completed before the economic assessment was started. Nevertheless, the economic

assessment was completed over a period of 12 months which was sufficient to develop a credible and useful analysis.

Compliance costs associated with the proposed standards were investigated and estimated for sources relevant to each of the three media. While the sources of exposure from different media were determined, anticipated benefits could not be allocated to air, drinking water or soil. Benefits were identified, quantified and valued in terms of the effects that revised environmental standards would have on blood lead levels in Ontario children and the associated effects on learning and lifetime earning capacity.

Ontario Drinking Water Objectives (ODWOs)

Drinking water objectives are incorporated as conditions in Certificates of Approval for water works. Local health authorities also refer to the ODWOs to determine whether the drinking water is safe for human consumption. Between 1991 and 1994, the provincial drinking water objective for lead was 10 µg/L (= 10 parts per billion).

Lead in drinking water results primarily from the corrosion of lead-containing components of drinking water distribution systems, especially pipes in households. Historically, lead pipes were used to connect households to water mains and lead solder was used extensively to connect copper pipes, although building codes now limit the quantity of lead in plumbing solder to less than 0.2%. Lead concentrations in most surface or ground water source supplies in Ontario were observed to be below 5 µg/L so as to not be considered a hazard (Ontario Ministry of Environment and Energy, 1994a).

Control technologies and strategies (risk management options) must be assumed in order to estimate compliance costs. For each control technology, basic information needed to estimate costs and derive cost functions include capital and operating costs at different levels of effort or control and the removal or reduction efficiency of the technology for the contaminants of concern.

Since most of the lead contamination in drinking water comes from the corrosion of pipes and fittings within private dwellings, three main technical methods or strategies to reduce the lead content of drinking water delivered to the consumer's tap include 1) flush pipes to remove standing water with elevated concentrations of lead, 2) replace lead-containing service lines and fittings and/or 3) reduce the corrosiveness of the water supply.

Flushing pipes each morning reduces lead concentrations in tap water by 95% or better. The cost of this technology is the extra water that is flushed away unless it is conserved for non-consumptive uses plus the time and effort it takes individuals to remember to flush their pipes each day. This cost can be reduced by storing flushed water in pitchers and bottles for drinking and using the first 10 minutes of tap water for non-consumptive purposes. Costs were not estimated for this approach.

Lead pipes are no longer installed by municipal distribution systems in Ontario but many old pipes are still in place in older homes. Municipalities replace lead pipes that connect houses to street mains only when other work is being done. The US EPA estimated that the cost to replace lead service pipes in homes ranges from \$900 US to \$1,800 US per household depending on local circumstances and replacement method (EPA, 1991 cited in Federal Register).

The corrosiveness of delivered water can be reduced by increasing the pH of the water through the addition of lime, caustic soda, sodium carbonate or sodium bicarbonate at the communal treatment process. However, changes in pH affect the performance and cost of other essential treatment processes such as disinfection and coagulation. Increasing the pH may also result in increased levels of trihalomethanes, which are potentially hazardous by-products of the disinfection process. Changes in pH may increase the degree of corrosiveness for other metals so that the consequences of changes in corrosiveness can vary widely from plant to plant.

To estimate total costs associated with reducing corrosiveness so as to ensure achievement of the Ontario Drinking Water Objective for lead, water distribution systems in which standing water lead concentrations were found to be in excess of 5 µg/L, a level identified as a health-based criterion from the risk assessment, were identified through the Ministry Drinking Water Surveillance Program. Of 128 distribution systems tested, 48 were found to have lead concentrations in excess of 5 µg/L. Costs to reduce corrosiveness in these 48 systems were based on the addition of lime softening and coagulation/filtration steps in the water treatment process although the coagulation/filtration component may not be necessary for large systems. Annualized costs were based on a 20-year amortization period at 8% interest rate.

Total capital costs to implement corrosion control programs in all potential plants (so as to ensure lead levels in tap water at 5 µg/L or lower) could range as high as \$1.5 billion for the province if both treatment technologies were added to all 48 systems (Ontario Ministry of Environment and Energy, Dec. 1994a). Annualized, these costs could amount to \$181.7 million per year. Annualized costs per household for corrosion control could range from \$5.94 to \$2,394, depending on the size of the municipality. Certain factors imply higher or lower costs at specific municipalities: small municipalities generally incur higher costs per household; large systems may not need the coagulation/filtration step; replacement of lead lines to houses during other work may be needed. In any event, flushing may still be needed to reduce lead levels due to leaching from pipes in homes.

It was recommended that the drinking water objective for lead remain at 10 µg/L due in large part to the high cost of controlling corrosiveness in water systems. While the 10 µg/L objective for lead is higher than a standard based strictly on risk, continuous exposure to this level represents an increase in total lead exposure of only 11% over the threshold defined by the IOC_{pop} (Ontario Ministry of Environment and Energy, Dec. 1994a).

Air Quality Standards and Guidelines

Half-hour mandatory standards at point of impingement (POI) are often specified in Certificates of Approval and are compared against air quality monitoring data to determine whether major sources are in compliance. Ambient air quality criteria (AAQCs) are not legally enforceable in and of themselves but are used in air quality indices, in environmental assessments of new projects and to evaluate the Ministry's air quality management programs. POI standards are set such that 24-hour and 30-day AAQCs are not exceeded.

Ambient air standards for lead are intended to help achieve long term reductions in the concentration in soils, surface waters and sediments as well as to protect susceptible groups and individuals from acute and chronic health effects due to inhalation.

Current sources of lead air emissions in Ontario are summarized in Table 2. While primary lead smelters account for the largest volumes of lead emitted to the air, exceedences of the ambient air quality criterion had, in the past, been recorded only in the vicinity of Ontario's two existing secondary lead smelters.¹² Consequently, despite relatively small emissions (5.9 out of 324 tonnes per year), secondary lead smelters were the only plants which might have had to implement additional direct emission controls as a result of a new ambient air quality standards.

Table 2

Sources of Airborne Lead Emissions into the Ontario Environment

Source/Industry	Emissions (Tonnes/year)
<i>Non-Ferrous Smelters and Refiners</i>	
Primary Smelters	211
Secondary Smelters	5.9
<i>Automotive Industry</i>	
Wet-cell Automotive Battery Production	51.1
<i>Petrochemical Products Industry</i>	
Metallic Additives	52.4
<i>Waste Disposal Industry</i>	
Semi-suspension Incinerator	2.4
Multi-chamber Incinerator	0.03
Fluidized-bed Incinerator	0.10
Multihearth Incinerator	0.90
Commercial and Industrial Incinerator	0.04
TOTAL	323.87
Source: Ontario Ministry of Environment and Energy, Dec. 1994a, p. 58	

Both stack and fugitive emissions of lead are released by secondary lead smelters. Stack emissions are normally vented through engineered collection systems and are relatively easy to control through the use of bag-house filters which can reduce lead particulate concentrations in the emissions stream to 11 mg/m³ or better (Environment Canada, unpublished consultant report, 1992). Fugitive emissions are generally the largest lead source from secondary lead smelters.

Estimates of costs for existing emission control technologies were produced for a model secondary lead smelter patterned after an operating plant in Mississauga (a suburb of Toronto), Ontario. This existing plant had recently installed systems to control lead emissions as well as an automated spraying system to suppress yard dust.

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The analysis indicated that it was technically feasible for the model smelter to achieve a monthly ambient air concentration of 0.7 µg/m³, measured at the maximum point of impingement, which was immediately adjacent to the plant property. The technologies that would be needed to maintain the 0.7 µg/m³ are summarized in Table 3. Capital costs (including engineering and design; purchase and installation of existing equipment, facilities or structures and feasibility studies) and yearly operating costs are summarized in Table 3 as well. The total capital costs for these systems were estimated at \$5.6 million in 1992 dollars. Operating costs (ie. energy requirements, materials, labour, and maintenance) were estimated to be \$985,000 per year.

It was noted that, of two operating lead smelters in the Toronto area, one plant had all of the systems and technologies listed in Table 3 installed while the other did not. Consequently, one plant would not have to incur any extra costs to comply with a point of impingement standard of 0.7 µg/m³ while the other would likely have to incur some or all of the capital and operating costs listed in Table 3.

Table 3

Emission Control Systems and Equipment Required in a Model Secondary Lead Smelter in Order to Achieve a Point-of- Impingement Concentration of 0.7 µg/m³

Equipment	Capital Costs	Yearly Operating Costs
Kettle bag-house	150,000	70,000
Paste building bag-house	200,000	60,000
Rotary furnace sanitary hood bag-house	150,000	60,000
Refinery roof bag-house	200,000	60,000
New electrically operated door(s) systems for entire facility to balance ventilation	50,000	10,000
Two vacuum sweepers	60,000	50,000
New paste storage building (including charge preparation)	750,000	10,000
Flue dust system	150,000	15,000
Truck tire washing facility	400,000	50,000
CX Phase I (including new wet battery breaking systems and re-vamping of building etc)*	3,500,000	600,000
TOTAL	\$5,610,000	\$985,000
Source: Ontario, Ministry of Environment and Energy. Rationale for the Development of Soil, Drinking Water and Air Quality Criteria for Lead. Toronto: Ministry of Environment and Energy, Dec. 1994a		

Available technologies to achieve even further reductions in lead emissions, especially fugitive emissions and lower average monthly or weekly average concentrations around a plant site, include re-

design of plant to minimize materials handling; hooding or enclosure of the entire plant to capture all fugitive emissions, purchase of a buffer zone around the plant to dilute off-site concentrations and relocate the plant to a less populated and sensitive area outside the city. Unfortunately, there was insufficient information to estimate the costs of these potential technologies on a model plant.

To be protective of the most sensitive receptor population to lead in air, children age 6 months to 4 years, a desirable risk-based ambient 30-day average concentration for lead was determined to be $0.05 \mu\text{g}/\text{m}^3$. Given that the model plant could achieve a 30-day average ambient air concentration $0.7 \mu\text{g}/\text{m}^3$ with all of the systems and equipment listed in Table 3, the implications for this concentration for health risk exposure and build-up of soil levels were examined.

If a 30-day average point-of-impingement concentration of $0.7 \mu\text{g}/\text{m}^3$ was established as a standard, continuous exposure at this level would increase total lead exposure by only 14% ($0.7/0.05 \times 1\%$) over the threshold defined by the IOC_{pop} . Moreover, emissions at the $0.7 \mu\text{g}/\text{m}^3$ level over 50 years would lead to an increase in soil lead concentrations of approximately 185 ppm around a plant. This soil concentration is below the 200 ppm criterion that was proposed for soil in residential areas (Ontario Ministry of Environment and Energy, Dec. 1994a).

To convert an ambient air standard based on a 30-day average concentration, to a maximum 24-hour and half-hour average concentration, the following empirically-derived conversion formula was used: multiply the 30-day average by three to get the 24-hour criterion and multiply the 24-hour criterion by three to derive the ½-hour POI standard. These values were deemed protective of human health from exposure through both direct inhalation and accumulation in soils.

Consequently, it was concluded that a secondary lead plant that has installed the technologies identified in Table 3 could achieve a proposed POI standard of $0.7 \mu\text{g}/\text{m}^3$ without incurring additional compliance costs.

Lead in Soil

At the time of this initiative, soil clean-up guidelines were applied under a decommissioning policy which imposed guidelines only when sites were decommissioned or land uses were changed, as from industrial to residential. The guidelines are not mandatory unless included in a control order or by a municipal building permit. These guidelines would not trigger abatement or remediation if concentration levels in a property are found to exceed the guidelines for a specific land use. Furthermore, lead is only one of a number of contaminants that are found in soil, each one having a clean-up threshold guideline.

As noted earlier, soil accounts, on average, for about 64% of a child's total intake of lead. A risk-based lead standard to protect children between 0.5 and 4 years was estimated to be 200 $\mu\text{g}/\text{g}$ or ppm in residential soils, assuming that dust and soil are the only source of soil-borne lead (Ontario Ministry of Environment and Energy, Dec. 1994a). If home-grown garden vegetables are considered to be a potential source of exposure in addition to intake through direct ingestion of soil and dust, the risk-based soil guideline for residential use would be reduced to 125 ppm. Therefore, the cost implications of two potential clean-up standards for residential land, 200 ppm and 125 ppm, were assessed.

Technologies and actions available to remove lead from soil are summarized in Table 4.¹³ Technologies of choice vary with the scale of the remediation project. For small sites, contaminated soil

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removal and replacement with clean soil is preferred and cost depends on the tipping fees at secured landfills as well as excavation and transport costs.

Typical costs are about \$160 per metric tonne where one tonne is approximately equivalent to a 10 metre square patch of soil excavated to a depth of 1 cm. For large soil remediation projects, soil washing can be applied. Soil washing has a removal efficiency of between 70% to 98% and can achieve residual soil lead concentrations of 100 to 200 ppm.

Table 4

Soil Remediation Technologies for Lead¹

Technology	Cost per tonne	Removal Efficiency	Comments
Soil removal	\$150-430	meets background soil concentration; can be coupled with soil replacement	contaminated soil disposed at landfill; costs are dependent on tipping fees ³
Soil washing ²	\$55-130	heavy metals 70% (to <200 ppm) lead 76%	best suited for sand and gravel; fine soils difficult to treat
Soil washing with chemical treatment and or EDTA chelation ²	\$55-130	heavy metals 67% (to 75-125 ppm) lead 75% (to 25 ppm) with EDTA treatment 94-97%	chemical augmentation can increase the efficiency of soil washing; EDTA soil washing demonstrated at pilot scale only
Electro-Reclamation ²	\$100-450	unknown	-

1. *Sources:* Remediation Technologies for Contaminated Soils, October 1992 MOEE Identification of Potential Health Concerns of Soil Remediation Techniques; November 1991, City of Toronto, Contaminated Soil Treatment Technologies, 1991, Consultant's Report Prepared for Health and Welfare Canada by Intera.

2. Excludes costs associated with excavation and soil handling.

3. Tipping fees at major landfills in Southern Ontario have been reduced since the Ministry rationale document was originally published.

The province has funded two soil removal and replacement projects involving lead (Ontario Ministry of Environment and Energy, Security Account Office, 1997). These two projects cost \$6.5 and \$3 million and were funded entirely by the Ontario Ministry of Environment and Energy. There has been no comprehensive inventory of contaminated soil clean-up projects and their costs to all sectors in Ontario.

In order to estimate the potential costs associated with changing the soil clean-up guideline for lead, a large-scale site remediation project was examined. One of the largest remediation projects in Ontario was a joint municipal-provincial plan, called Ataratiri, to redevelop a 32-hectare industrial site in the downtown Toronto core into a residential community. Approximately 50% of the soil at the site exceeded the soil clean-up guidelines for one or more parameters. The estimated total cost of remediation was about \$160 million (City of Toronto, 1991).

Based on an analysis of 767 soil samples tested for lead at the site, the consequences of reducing the soil clean-up guideline from 500 ppm to 200 ppm would be a 20% increase in the number of samples failing to meet the criterion. Reducing the soil clean-up guideline to 125 ppm would result in a doubling (100% increase) of the number of soil samples failing to meet the criterion. Assuming that clean-up costs are directly related to the number of soil samples taken which exceeded the clean up criteria, then a clean-up criterion of 200 ppm could increase clean-up costs by about 20% while a criterion of 125 ppm could result in an approximate doubling of remediation costs. It was judged that the incremental cost implications of imposing a 125 ppm clean-up standard for residential soils would be excessive given the uncertainties associated with estimating the degree of lead exposure which results from home-grown vegetable consumption (Ontario Ministry of Environment, Dec. 1994a).

Soil clean up and decontamination reduces risks and liability associated with a contaminated property. Reduced risks and liability in turn enhance the demand for properties and result in higher property prices. The net private benefit to a property owner is the property price after clean up, minus the price before clean-up, minus clean-up costs. Application of clean-up guidelines is often required by lending institutions for properties that are contaminated. Assessments of interactions among clean-up levels, costs, liability and property prices are presented in a report by the Ontario Ministry of Environment and Energy (July 1994) but are not reviewed here. Standard setting for lead in soils is also complicated by the fact that, in Toronto, like many other cities, yards around many older homes have soil lead levels in excess of 200 ppm due to the historical use of lead in gasoline and paint.

Consequently, a lead soil concentration guideline of 200 ppm ($\mu\text{g/g}$) for residential land use was recommended. A key consideration was the judgement that the costs of a residential guideline of 125 ppm would be financially burdensome. While, these guidelines are not mandatory, they are often required by municipalities, lending agencies or by insurance underwriters to limit liability.

The potential benefits associated with these various standards are discussed in the next section.

Benefits Assessment for Multimedia Lead Standards

Assessment of the benefits of reducing and preventing lead exposure in Ontario by means of the proposed lead standards focussed on preventing and reducing exposure to children aged 4 years or less. These standards are also intended to prevent an excessive accumulation of lead in soil and sediments over time. Benefit estimates were quantified in natural physical units and then valued in monetary terms. Therefore, where possible, benefit estimates consist of two distinct sets of information:

- 1) Empirical estimates of the biophysical effects and consequences that result from remedial actions are presented. These estimates show explicitly the types of effects, their magnitudes in relevant biophysical units and how relevant biophysical data are used to

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determine the magnitude and distribution of the beneficial effects of a decrease in lead exposure and,

- 2) Monetary values associated with the various quantitative benefit categories.¹⁴

Keeping the two sets of estimates separate allows reviewers and stakeholders the opportunity to assign their own explicit weights or values to the relevant bio-physical benefit measures if they disagree with those that result from the use of monetary values.¹⁵

Benefit Identification

Children four years or younger are the target population for protection against lead exposure. The benefits of reducing lead exposures from all of the sources that may be subject to the various standards include: 1) reductions in elevated blood lead levels below 10 µg/dL, a level associated with an increased risk of chronic health effects, 2) reduced adverse health risks and effects, and 3) increased learning and earning abilities.

Other potential benefits, such as avoiding the emotional damage to families of having a lead poisoned child or preventing other health-related problems resulting from lead exposure, could not be estimated with available information. In addition, few, if any, cases of clinical lead poisoning (ie. where blood lead >25µg/dL) in Ontario are caused by direct exposure to soil, drinking water or air-borne sources of lead. Because the standards considered in this exercise did not address acute lead poisoning from lead-based paints, avoided damages and costs associated with these effects were not considered.

Valuation of Benefits

As noted, these benefits can be valued in terms of reduced medical costs and expenses and increased lifetime earnings. However, since there are few cases of acute lead poisoning resulting from the media included in this exercise, no reduced medical expenses are likely to be associated with more stringent lead standards. Consequently, lifetime earnings became the focus of the effort of value benefits associated with the proposed lead standards.

To calculate the net present value of lifetime earnings, dollars available in the future must be discounted to the present. A 5% real discount rate was used in the analysis. It was assumed that real wages would grow by 1% per year due to productivity growth only. Historically, productivity increased by 1.9% in Canada between 1980 and 1990. In 1993, the Ontario Ministry of Finance and a number of other business organizations forecast productivity growth to vary between 1% and 2%.

The computational method used to estimate the present value of expected earnings for a 4 year old in Ontario through to age 77, the average life expectancy of Ontario citizens, is

$$V_4 = \sum_N^{77} \frac{Y_N (1 + X)^{N-4}}{(1 + r)^{N-4}}$$

where

Y_N = the average annual earnings at age N. Estimates were obtained from Statistics Canada, Catalogue 13-207, *Income Distributions by Size in Canada, 1991*

X = assumed annual increase of 1% in earnings due to productivity increases. This factor is added to the equation to allow for the fact that in a growing economy individuals may expect an upward trend in their earnings. It is an adjustment for the growth in productivity in the economy not for the inflation. It is assumed that real wage growth in the future will be 1% per annum

r = the discount rate of 5%.

Empirical Quantification and Valuation Procedures and Information Requirements

Quantification of the beneficial consequences of the standards for Ontario involved examination of the effect that revised environmental standards could have on children's blood lead levels and the number of children potentially affected in the province. Empirical derivation of these relationships is associated with substantial uncertainty.

The benefits assessment approach was adopted from the Centre for Disease Control (CDC) (1991) statement on preventing chronic lead poisoning in young children. This method postulates sequential, cause-effect relationships among: 1) blood lead levels and intelligence (measured by IQ); 2) IQ and educational attainment, and 3) educational attainment and lifetime productivity (measured by life-time earning potential).

Relationship number 1, between blood lead levels and IQ, was determined to be a reduction of 0.25 IQ points for every 1 µg/dL increase in blood lead based on the CDC (1991) study. This relationship assumes that there is no threshold below which blood lead levels do not affect IQ.

Relationships 2 and 3, among IQ, educational attainment and earning potential, were derived from relationships between IQ and the level of educational attainment and from relationships among educational attainment, labour force participation and wage rates. Using Ontario data on historical lifetime earnings, the lifetime benefit of reducing blood lead by 1 µg/dL was estimated at \$1,852 per child affected (expressed in 1993 dollars).

Other factors besides lead blood levels affect a child's level of educational attainment. While exposure to lead has an indirect affect on cognitive ability, other factors such as nutrition, parental involvement, socio-economic status, effectiveness of a teaching system can all influence the level of educational attainment and thus lifetime earning potential of a child. Lead exposure and blood lead levels explain only a portion of the level of educational attainment achieved by a child. Therefore, values estimated likely over-state the value of the potential benefits.

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The CDC (1991) also presented estimates of the benefits of preventing lead exposure caused by ingesting lead-based paint which are associated with blood lead levels above 25 µg/dL and so included avoided medical and special education expenses associated with acute lead poisoning. However, as noted, these estimates were not considered relevant to the potential benefits of revised standards for the environmental media covered in this exercise. (Ontario Ministry of the Environment, Dec. 1994a).

The CDC approach produces estimates of the reduced increased lifetime earnings resulting from a reduction in lead exposure from all potential sources. Consequently, these estimates cannot be linked to reductions at any specific source or to any of the media-specific standards.

Relationships Between Environmental Standards/Guidelines and Blood Lead Levels

Table 5 provides a comparison of blood lead levels which are predicted to result from various exposure scenarios concerning levels of lead in food, ambient air, soil and drinking water.

As shown in Table 5, blood lead levels of children across Ontario averaged between 3.8 and 4.3 µg/dL. Nevertheless, about 4% of those sampled had blood lead levels 10 µg/dL or higher. A predictive model was applied to estimate blood lead levels based on scenarios that assumed different configurations of source contributions. Assuming 1993 lead levels in food and reasonable intake amounts from environmental sources, the predicted daily lead intake for children in Ontario was estimated to be 1.9 µg/kg/day which roughly translates to a blood lead level of 5.0 µg/dL. A child maximally exposed to the current standards and guidelines for air, soil and drinking water in 1993 would be predicted to develop a blood lead level of 11 µg/dL.

Conversely, a child maximally exposed to the revised standards and guidelines would receive a daily intake of 2.25 µg/day which translates to a blood lead level of 5.9 µg/dL, or a difference of 5 µg/dL. Multiplying this estimate by \$1,852, the lifetime value of earnings gained by reducing the blood lead level by 1 µg/dL per child affected, yields a potential lifetime benefit value of \$9,260 per child.

The final step was to estimate the number of children who could benefit from the revised standards. Blood surveys indicated that 4% of children have blood lead levels in excess of 10 µg/dL. In Ontario, this represents approximately 18,000 children living in urban areas who are potentially at risk of chronic health effects (Ontario Ministry of Environment and Energy, March 1994). If all 18,000 children actually benefit from the revised lead standards, the total value of the benefits to Ontario, expressed as the present value of lifetime earnings to age 77, would amount to about \$166 million. This estimate is considered a maximum value.

Table 5

Exposure Estimates and Predicted Blood Lead Concentrations of Various Exposure Scenarios for Children 4 years or Younger

Exposure Scenario	Source Contribution (µg/kg/day)		Daily Intake (µg/kg/day)	Predicted Blood Lead Concentration (µg/dL)
Actual - based on results from 1990 blood lead surveys	N/A		N/A	4.3 ² 3.8 ³
Predicted - based on 1985 food basket survey	Food	1.33	2.77	7.5
	Soil ¹	1.2		
	Drinking Water	0.23		
	Air	0.01		
Predicted - based on projected 1993 food levels	Food	0.45	1.89	5.0
	Soil ¹	1.2		
	Drinking Water	0.23		
	Air	0.01		
Predicted - based on maximal exposure to current guidelines	Food	.45	4.31	11
	Soil ¹	3		
	Drinking Water	0.46		
	Air	0.4		
Predicted - based on maximal exposure to proposed guidelines	Food	0.45	2.25	5.9
	Soil ¹	1.2		
	Drinking Water	0.46		
	Air	0.14		
Source: Ontario Ministry of Environment and Energy, Dec. 1994a, p. 67. 1. Soil contribution does not include exposure via backyard vegetable consumption. 2. Mean - South Riverdale Abatement Study control group (1990). 3. Mean - Ontario Blood lead survey (1990).				

These estimates are subject to three sources of uncertainty: 1) some potential benefit categories associated with reduced lead exposures could not be quantified or valued (an under-estimating uncertainty) 2) the relationships among the revised standards, reduced lead releases, exposure and

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changes in blood lead levels (can bias estimates in both directions) and 3) the number of children actually benefited by revised standards (an over-estimating uncertainty).

The second and third uncertainties derive from the fact that children are exposed to lead from many different sources. For those 18,000 children who are estimated to have blood lead levels greater than 10 µg/dL, distinguishing between the contribution made by environmental sources (soil, drinking water and air) and that from ingestion or inhalation of lead-based paints, consumer products and food was, and is, impossible. Moreover, research up to 1994 had not found a robust relationship between soil remediation projects and a subsequent decline in blood lead levels in children (Ontario Ministry of Environment and Energy, Dec. 1994a).

Consequently, the proposed revised standards for lead would result in little immediate change in the prevailing exposure for most people in Ontario. For example, while lead exposure via soil represents the single largest source of exposure (65% of total potential exposure from all media), the proposed revised clean-up guideline would not result in reduced concentrations in urban properties with elevated soil lead levels or reduced exposure to individuals living near these properties until such times as the property is sold for redevelopment as residential use or parkland. At that juncture, the municipality or the lending institution may require soil clean-up. The standards are intended primarily to prevent future adverse effects and, around point sources such as battery recycling plants, compliance with the standards will protect against human health effects.

Because of the above-noted uncertainties, potential costs of compliance with the proposed standards were judged likely to be much lower than the maximum values estimated. Moreover, the benefits to Ontario children between 6 months and 4 years which were quantified and valued are likely to be lower than the 18,000 children and the \$166 million in benefits estimated earlier. On the other hand, benefits which were not quantified and valued imply that total benefits were under-estimated.

Conclusions and Lessons Learned

The **costs** associated with each proposed revised standard are summarized as follows:

1. **Drinking Water Objectives** - It was recommended that there be no change in the standard. This recommendation was based, in part, on the high costs of the available technologies to reduce or prevent lead from leaching from pipes in residences: e.g. reduce corrosiveness at 48 municipal water systems, up to \$1.5 billion in capital and up to \$182 million total annualized cost (as much as \$2,400 per household); Replace lead service pipes, could cost between \$900 and \$2,000 per household. No inventory of lead service pipes between water mains and houses available on which to base cost estimates.
2. **Air Quality Standards and Criteria** - The total costs for the equipment and systems that could be installed in a model secondary lead smelter to achieve the proposed point of impingement (POI) limit of 0.7 •g/m³ were estimated to be as much as \$5.6 million in capital and \$985,000 per year in operating costs. One of two secondary lead smelters operating in Ontario did not have these systems installed. Consequently, no incremental compliance costs would be needed for the smelter that had already installed equipment and systems.

3. Soil Clean-up Guidelines - As promulgated in Ontario, guidelines do not trigger clean-up unless land use is being changed to residential or park uses. Costs of achieving a 125 ppm clean up guideline were judged to be excessive when compared with anticipated benefits and associated uncertainties. Clean-up guidelines are generally required by lenders, property buyers and bonding companies for non-residential properties. Projects can cost millions but will be spread over time and incidence.

The **benefits** of the more stringent air, drinking water and soil clean-up standards and guidelines, in terms of enhanced educational attainment and higher earnings, could accrue to as many as 18,000 Ontario children between the ages of 6 months and 4 years, over the next 77 years. The total monetary worth of these beneficial consequences could be as high as \$166 million, in present value terms. However, because of the number of people whose exposure will actually be reduced as a result of the revised standards is expected to be less than the maximum number noted above, the likely direct benefit value would be lower than \$166 million.

In the case of the lead and other standards, economic analyses were applied to balance the potential benefits against the likely compliance costs of risk-based or effects-based standards and to judge whether compliance costs might be financially disruptive to parties liable to the standards. In the case of the drinking water objective, the recommendation to leave the standard unchanged was due, in large measure, to the potentially large cost associated with reducing corrosiveness of water in treatment plants as well as the low likelihood of achieving significant risk reductions among water consumers (Ontario Ministry of Environment and Energy, Dec. 1994a).

The economic analyses were an integral component of the “rationale document” which was published by the Ministry and used for public consultation on the lead standard. The assessments for the lead standards and for other standard setting exercises are always carried out by interdisciplinary teams. The economic assessments also identified stakeholders who would most likely express concern about proposed standards because of the costs that could be imposed on them. Inclusion of economic assessments in the rationale document also helps to limit, and provide responses to, unsupported claims and complaints about the financial effects on stakeholders liable to the requirements.

Cost estimates of environmental initiatives and standards are usually produced by Ministry staff (engineers and economists) or by consultants commissioned by the Ministry. Industrial stakeholders are invited to comment on the estimates and provide revised estimates that are suitably documented. However, few industry spokespersons have provided alternative cost estimates that are sufficiently documented so as to permit an understanding of the estimation procedure. Moreover, only a few large industry associations and Ontario Hydro, the former provincial crown corporation that, until 1999, generated virtually all of the electricity for the province, have commented substantively on the benefit estimates

Studies to evaluate the accuracy of the economic or other proactive and predictive analyses are seldom done. Donnan and Cercone (1997) compared the estimated costs of a mandatory monitoring program for industrial waste water effluents with the results of a survey of actual expenses incurred. This is the only retrospective evaluation of an environmental economics nature that has been completed in Ontario. Unfortunately, there appears to be little demand for such evaluations at this time. Moreover, such studies involve costly surveys and questionnaires which can be difficult to justify.¹⁶

Critical features of an effective economic analysis for use in environmental protection and risk management decision-making include: 1) interdisciplinary teamwork, 2) involvement of economists at the beginning of the process, 3) dialogue with and feed back from key decision-makers at least once during the analysis, 4) resources to commission consulting studies as needed, and 5) dialogue and feed-back from stakeholders.

A socio-economic assessment may not be necessary for every standard, initiative or risk management decision. In the context of ambient quality standards, if prevailing ambient concentrations of a compound are well below the proposed standard, further assessments may not be necessary. Socio-economic assessments are needed especially when individuals or groups claim that they will be adversely affected by proposed standards. Some sort of trigger is needed to initiate economic assessments for appropriate issues. In the U.S., successive presidential Executive Orders require federal agencies to apply a benefit-cost analysis to regulations, standards and programs that will impose costs greater than \$100 million on the economy (Howard and Benfield, 1991).

The authors have prepared an economic assessment framework to evaluate proposed Canada-wide harmonized standards under the auspices of the Canadian Council for Ministers of the Environment.¹⁷ Five criteria have been proposed to help determine whether the economic assessment framework should be applied: 1) when stakeholders liable to the standard complain about financial or economic hardship and can provide documentation to verify their contention, 2) when costs of complying with standards exceed a pre-set dollar threshold as is done in the U.S, 3) when ambient concentration thresholds (e.g. “no environmental effects” or “no human health effects”) are not apparent (ie. dose-response functions are linear to the origin), 4) when there is a demand for stringent, costly standards with uncertain effectiveness or benefits and 5) when there is a possibility that more stringent standards could be achieved at lower costs than indicated by preliminary estimates.

Agencies like the OECD can help develop and sanction harmonized analytical and estimation methods that are contentious such as the value of life and other non-priced attributes. Citing methods and computational procedures that are endorsed by the OECD give added credibility to the results in the eyes of some stakeholders and government agencies. Publishing documented case studies is helpful as well.

Application of economic analyses to environmental protection issues, including standard setting, in Ontario has been contentious at times and such analyses have not been altogether conclusive or comprehensive. Nevertheless, they have helped make and support decisions about environmental standards, abatement requirements, program designs and policy development. Completion of economic analyses will always facilitate more informed decisions and this is always desirable.

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Endnotes

1. In October 1997, the Ministry of Environment and Energy was reorganized. The “Energy” component was reassigned to a new Ministry of Energy, Science and Technology.
2. All new policies and regulations must be subjected to a “Regulatory Impact and Competitiveness Test”.
3. As a result of the reorganization in October 1997, staff in the former Economic Services Branch, including one of the authors (Donnan), were transferred to the new Ministry of Energy, Science and Technology.
4. Only the rationale documents for Tritium (Ontario, Dec. 1994b) and Lead (Ontario, Dec. 1994) have been released to the public.
5. This framework document may be found at: http://www.ccme.ca/ccme/3e_priorities/3ea_harmonization/3ea2_cws/3ea2.html
6. Violation of non-enforceable objectives or guidelines cannot be prosecuted. However, the Ministry can specify the non-enforceable criteria, objectives and guidelines as conditions in statutory instruments such as ministerial orders or “Certificates of Approval” (permits) issued to individual pollution sources, in which case they would be legally enforceable.
7. Risk refers to the likelihood that a human injury or adverse effect can be caused by a substance, technology or activity. Risks, which are calculated for individuals or population, are often stated as numeric probabilities such as “1-in-1,000,000 lifetime cancer risk associated with exposure to contaminant X.”
8. Guidelines and Standards include half-hour Point-of-Impingement standards for air, Ontario Drinking Water Objectives, Ambient Air Quality Criteria and soil clean-up guidelines.
9. Certificates of Approval are permits required, under the Ontario Environmental Protection Act, of any corporation or person who handles, transports, emits, discharges, treats or disposes of residual pollutants including liquid and solid industrial wastes, sewage, air-borne pollutants and certain types of solid wastes including mixed municipal wastes. Certificates of Approval generally contain environmental performance conditions and can require that financial assurance be provided to the Ministry to ensure that funds will be available to complete required abatement actions, close landfill and other waste processing and disposal sites properly and provide long term care, maintenance and monitoring of closed disposal sites.
10. The Advisory Committee for Environmental Standards was dissolved in 1995 after serving for about 3 years.
11. Approximately 3-4% of children in Ontario have blood lead levels in excess of 10 micrograms per deca litre ($\mu\text{g/dL}$). This estimate is based on blood lead surveys of school age children conducted during 1990 and 1992.

12. Furthermore, a few exceedences have been observed near the demolition sites of old buildings. These exceedences are likely due to the mobilization of dust from lead-based paints.
13. Technologies that immobilize lead in the soil matrix are not generally used in Ontario and were not considered further.
14. The use of monetary units to value environmental damage or benefit estimates is contentious but has the following advantages: 1) monetary values permit the addition of effects and consequences that are otherwise measured in diverse units; 2) monetary values represent the relative economic and (in some instances) social welfare associated with the various benefits, and 3) monetary values allow direct comparison of the value of beneficial effects with remedial action cost estimates in a benefit-cost assessment context.
15. Weighting units or "value measures" other than money have been suggested in the literature. However, monetary values are based on well developed theory, are widely understood and are less likely to involve assertion of researcher value judgements than non-economic weighting units.
16. Economists at Resources for the Future are currently carrying out a retrospective study of regulatory costs in the U.S (Morgenstern, 1997). Statistics Canada can enter into joint projects with paying partners to develop and implement surveys to evaluate regulations and requirements. Statistics Canada currently conducts a survey of expenditures on environmental protection and abatement by the public and private sectors.
17. As noted earlier, this framework is completed and can be downloaded from the web from: http://www.ccme.ca/ccme/3e_priorities/3ea_harmonization/3ea2_cws/3ea2.html.

Integration of an Economic Growth Model and Pollution Health Risk for Backcasting Japan's Desulfurization Experiences

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Introduction

According to the OECD's country review, *OECD: Environmental Policies in Japan* (1977), as well as numerous economic model analyses, Japan's pollution control measures are reported not to have decelerated economic growth despite their requirement for heavy investment.

In reality, Japan's industry invested heavily in pollution control. In 1975, investment for pollution measures accounted for 18% of capital investment and 6.5% of GDP. However, such investment accelerated technological innovation, raised product quality and lowered technical costs. For instance, high-efficiency engines were born as the result of automobile exhaust gas regulations, and R&D investment in pollution response reduced the cost of technologies in areas such as flue-gas desulfurization facilities. Moreover, the creation of effective demand boosted manufacturers of such pollution control equipment. Their actual production results reached 700 billion yen in 1975, and in the same year aggregate pollution control investment approached 1 trillion yen.

As a result, despite heavy investment in pollution control a rise in product costs was suppressed, and a macroeconomic influence was barely visible. This phenomenon is analysed with the use of a detailed economic model, whose results are published in the 1977 *Report on Quality of the Environment in Japan* as follows: "The economic effects of pollution control investment vary from one industry to the other, but it can be inferred that such investment was not so disruptive to the macroeconomy during Japan's period of past rapid economic growth. (Moreover, the OECD's report, *Environmental Performance Reviews: Japan*, says that, "it is interesting to note that they all suggest that the impact of relatively high pollution abatement costs on macro-economic magnitudes, such as GNP, employment, prices, and foreign trade, is practically negligible.")

When investigating factors that kept economic growth from decelerating, it is necessary to consider the fact that Japan produced almost no energy resources domestically, while effective demand created by pollution control investments was absorbed domestically, thus eliminating the need to rely on imports of pollution control devices. The opinion that Japan unified pollution response with economic growth has now become an established theory.

Yet many questions concerning the past relationship between pollution measures and the economy in Japan have remained unanswered. Examples of systematic research explaining the factors which combined to generate the results of Japan's pollution response and how the market was involved, for example, are rare. In particular, no systematic research has been found so far about the relationship

between health risks/damages and economic growth in Japan, while Japan had introduced a very unique compensation system for pollution related health damage. Furthermore, was Japan's pollution response implemented as a result of ideal timing, as is assumed? Or would there have been a better time to introduce pollution measures? What would have happened had implementation been delayed? And did Japan's pollution response succeed economically? No research to date has answered these types of questions.

In order to clarify the above questions, this paper estimates a health damage function of air pollution based on the compensation data in Japanese, incorporates it into an economic growth model, and then applies the model to reproduce the history of Japan's air pollution measures with a focus on sulfur dioxide reduction measures.

Outline of the Economic Growth Model

To re-enact the history of Japanese air pollution measures, an economic model was developed based on the MERGE model, which was jointly developed by Alan Manne of Stanford University and Richard Richels of the United States Electric Power Research Institute. MERGE is a dynamic optimization model which focuses on the equilibrium of energy supply and demand. It is designed using a combination of an energy model (ETA) which reproduces determining mechanisms for energy mix and an economic model (MACRO) which reproduces the relationship between economic growth and energy consumption. MERGE was modified for use in Japan, incorporating a pollution investment module and pollution damage function module.

In order to calculate the sum of damages resulting from sulfur dioxide emissions in Japan, a damage function was inferred from actual compensation to pollution-related health victims in Class 1 areas under the system of compensation for pollution-related health damage. Damage to health is by nature irreparable, and even cash compensation could by no means make amends. Because of this, it is important to bear in mind that the following estimates represent simply one trial calculations. This damage function, which estimates health-related damage sums based on sulfur dioxide emission volumes, was built upon the following type of equation:

$$\begin{aligned} & \text{Health-Related Damages (\$US)} \\ & = \text{Health-Related Damages per Victim (\$/person)} \\ & \times \text{Number of Victims per Ton of Sulfur Dioxide Emission Volume (person/ton)} \\ & \times \text{Sulfur Dioxide Emission Volume (tons)}. \end{aligned}$$

Figure 1 demonstrates the relationship between health-related damages per health victim and GDP per person, based on Japan's actual compensation data.

Damages were formulated using a logistic function. Moreover, Japan's actual compensation data gives us a value of approximately 0.1 persons for the number of victims per ton of sulfur dioxide. While applying this required damage function to estimate damages resulting from Japan's sulfur dioxide, we have estimated a dynamic of optimal sulfur dioxide reduction measures when damages are internalized by the market by building such damages into the economic model's calculations of the national economy.

Based on this model, we are able to simulate the following three conditions of sulfur oxide emission volume reductions, and systematically reproduce the process of Japan's past sulfur oxide measures.

- 1) Reduction in sulfur dioxide exhaust by flue-gas desulfurization: By adding a pollution investment module, we were able to calculate an equilibrium resolution for flue-gas desulfurization investment.
- 2) Reduction in sulfur dioxide emissions through sulfur reductions in fuel: Using the energy selection module, we were able to classify fuel according to sulfur content and calculate an equilibrium resolution for energy mix. Here, a price rise as a result of domestic heavy oil desulfurization investment is reflected in the price of low-sulfur crude oil.
- 3) Reduction in sulfur dioxide emissions by energy conservation and structural conversion of industry: Based on changes in the energy efficiency improvement coefficient and the effect of the production function's energy substitution elasticity rate, we were able to calculate the effects of emission reductions resulting from energy conservation and structural conversion of industry.

Through the use of this economic model, we have simulated the following:

- 1) Results of absolutely no implementation of Japan's response policies;
- 2) Timing for enactment of measures generating maximum economic efficiency;
- 3) Revenue/expenditure associated with loss and gain when the implementation of measures is delayed.

Figure 2 verifies the accuracy of this model by applying it to a comparison of calculated results with actual investment sums for flue-gas desulfurization. Given Japan's actual sulfur dioxide emission volumes as a restriction condition, this model reproduces the three mechanisms mentioned above, and of all the simulation's results it displays only output for flue-gas desulfurization investment. Investment sums here and all subsequent amounts are shown at 1990 prices, with conversion rate at approximately 1 dollar per 140 yen. This figure demonstrates an accurate reproduction of Japan's past flue-gas desulfurization investment history, as well as its past history of sulfur reduction in fuel.

Primary Factors Underlying Japan's Sulfur Dioxide Reduction

First, factors of Japan's reductions in sulfur dioxide emissions were analysed by reproducing the actual effect of Japan's sulfur dioxide reduction measures.

Figure 3 indicates the results of this simulation. The lowest line on the graph represents the reproduced value for actual sulfur dioxide emission volumes. The second line from the bottom represents estimate values for incremental sulfur dioxide emission volumes where flue-gas desulfurization investment is not carried out. The next line represents estimate values for incremental emission volumes when fuel sulfur content reduction is not executed. The next line represents estimated values for incremental emission volumes in the event that absolutely no energy conservation occurs, and the highest line represents estimate values for incremental emission volumes when the past industrial structure centered on heavy industry is maintained without conversion.

Had absolutely no sulfur dioxide reduction measures been carried out in Japan, it is estimated that emission volumes would have increased rapidly to more than seven times the actual peak. We understand that actual emission volumes were suppressed to a much lower level as a result of various measures.

Figure 3 shows the main factors contributing to a reduction in sulfur dioxide emissions. In the 1960s, reduction measures focused almost entirely on fuel conversion, while the effects of flue-gas desulfurization started to appear significantly at the beginning of the 1970s. Energy conservation's effects also had a significant influence on the situation. We further notice that the effectiveness of measures to reduce sulfur dioxide varied dramatically according to the level of policy progress, energy prices, and other external factors.

Continuously healthy market competition in Japan was also a main factor in the effective introduction of such measures. Additionally, oil's dramatic price rise after the oil shock inspired investments in energy conservation, which is seen to have had an effect on subsequent pollution measures. Further, fuel conversion to low-sulfur resources was influenced by the price of low-sulfur crude oil on the international market. Industry competition's drive towards technological innovation and cost reduction also influenced the popularization of flue-gas desulfurization technologies.

However, Japan's market competition was sustained by so-called "convoy fleet method" policies, which take as their principal object the promotion of domestic industry and a avoidance of the creation of definitive losers. This differs from international market competition based on the WTO (World Trade Organization) system. The government's subsidy policies have supported industry's pollution policies based on the "convoy fleet method". Moreover, the consolidation of an environmental monitoring system eliminated "free-riders" who ignore regulations, and this was also a significant factor in the promotion of market competition.

Timing of Measures to Reduce Sulfur Dioxide

Was Japan's air pollution response timed appropriately? Generally speaking, Japan's pollution control investment peaked in the 1970s, before the economy stabilized. Air pollution control investment in particular achieved an all-time high in 1975 and sharply decreased beginning in 1977. What would have been the result had the timing of such investment been delayed? Further, taking pollution-related damage into consideration, would investment have been timed earlier if economically rational policies had been carried out? To answer such questions, two types of simulations were conducted.

The first simulation calculates results according to a model where timing for sulfur dioxide emission restrictions is delayed - one case at six years and the other at ten. When the timing is delayed, GDP increases in the short term, but alternatively sulfur dioxide emission volumes as well as damages increase. The balance between these two was simulated according to the model.

The second simulation builds damages incurred as a result of sulfur dioxide emissions into national economic accounts under the economic model. It estimates the optimal timing for sulfur dioxide reduction measures when damage costs are internalized by market principles, assuming that factors such as flue-gas desulfurization technology costs and the state of technology remained unchanged over a 10-year range. When the timing of measures is hastened (to precede the actual timing), the possibility of a drop in GDP is high. On the other hand, sulfur dioxide emission volumes are reduced and so are resulting damages.

Figure 4 contrasts sulfur dioxide emissions generated by two cases of delayed response. Examining the situation in terms of economic gain and loss, Japan's air pollution response should have been timed much earlier.

In order to analyse the extent to which response timing should have been accelerated, a comparison of timing in flue-gas desulfurization investment (Figure 5) was conducted. These results could vary slightly as a result of the state of technology at the time, but they suggest at the very least that Japan should have executed air pollution response measures more quickly.

In Figure 6, each case produces significant differences in estimates for damages resulting from air pollution. In the cases where timing was delayed, damages peak at 2-3 times their actual amounts. In the case of optimal timing for the introduction of response measures, damages were suppressed to an extremely low level throughout all periods. Japan's timing in implementing air pollution measures was late, but it can also be said that any further delay could have caused severe damage.

Judging from an economic viewpoint, it can be said that although Japan responded to air pollution somewhat belatedly, it still managed to contain the situation in time.

Economic Loss and Gain Calculation of Air Pollution Prevention Measures

Finally, we shall apply the simulation results to an evaluation of the costs and benefits of Japan's air pollution response.

Figure 7 adjusts response timing compared with Japan's actual history of response timing, estimating differences in GDP and damage as well as resulting differences in net profits. Damages and net profit are calculated at 1990 prices, with conversion rate at approximately 1 dollar per 140 yen.

It can be said that this loss/gain calculation is integrated, in that it considers such factors as long-term influences upon economic growth and prevailing effects on energy consumption. However, this calculation does not consider two important factors.

The first is irreversible, cumulative damage caused by air pollution to human health. Although such damage represents a far greater value than the damage function considered here, we do not examine it due to severe limitations in our ability to translate such damage into economic cost.

The second is the effect of air pollution response on boosting GDP. Even in Japan's history of pollution response, there are many examples where pollution measures inspired technical innovation and dramatically lowered the cost of pollution response. For example, technological innovation as a response to environmental policies resulted in improvements in engine performance, the promotion of energy conservation and popularization of the material-closed system. As a result, the cost of the pollution measures has significantly declined.

On the other hand, an increase in pollution control investment cultivated Japan's environmental protection industry. For instance, an almost 1 trillion yen of investment in 1975 led to industrial growth of 4.5 trillion yen (3% of GDP at that time). Afterwards, the environmental protection industry attained stable demand. Its cost-benefit analysis is not conducted here because it is extremely difficult to reproduce the positive effects of technical innovation and the environmental protection industry's growth on the economy with the long-term equilibrium models that we have employed here.

Even considering the limitations of such models, Japan's air pollution response is nevertheless shown to come out on the positive side of a loss/gain calculation in economic terms.

Application to Other Asian Countries

Many Asian developing countries place a high priority on sulfur pollution issues, and want to analyse the interaction between environmental pollution damages and economic growth. This economic growth model was applied to Korea and China to predict the timing of investment in desulfurization stack gas devices.

Figures 8 and 9 show the results of these projections. The damage function or cost of increased SO₂ emissions rises rapidly along with economic growth and stimulates initial changes in the energy mix to reduce SO₂ emissions. Further reduction in SO₂ emissions requires substantial investment in desulfurization technologies as shown in the figures. Figure 8 indicates that Korean investment in these technologies is expected to rise in the mid 1990s, whereas Figure 9 shows increased Chinese investment in these technologies occurring before 2020.

The results of this SO₂ evaluation show that the economic model could be effectively used in developing countries, if important characteristics of developing countries can be carefully reflected to the model. We are trying to improve this model and to link it to our integrated assessment model, namely the Asian-Pacific Integrated Model (AIM), in order to clarify the effects of policy integration of SO₂ and CO₂ reduction in developing countries and to clarify the cooling effect caused by sulfur aerosols.

Conclusion

As a result of this analysis, the following conclusions were reached.

Japan's first air pollution measures were those reducing fuel sulfur content in FY 1964. Various fuel conversion and energy conservation measures have since been devised. Among them, flue-gas desulfurization measures peaked (when viewed in terms of investment sums) in 1974.

When we take the year 1974 as a standard and consider the theoretical effect of response timing, it is estimated that damages resulting from air pollution would have exceeded an estimated cumulative amount of 12 trillion yen had response been delayed by 10 years. The rise of GDP over this period would have stopped short of 6 trillion yen, indicating an overall loss of approximately 6 trillion yen. Even had the timing been delayed by only six years, losses of over 1 trillion yen would have been incurred.

On the other hand, had response timing been accelerated by about eight years, it is highly likely that a resultant decline in damages would have exceeded a resultant decline in GDP, making this more economically profitable than the actual case.

Although Japan's air pollution response was somewhat late, the dramatic rise in air pollution prevention investment during the 1970s eased and eliminated previous pollution damage. We can say that consequently an anticipated subsequent rise in damages was pre-empted. In the end, Japan's air pollution response was economically profitable.

Further, had Japan's air pollution response been delayed, difficulties might have arisen not only in terms of damage, but also in terms of focused pollution prevention investment. In the 1980s many

industries initiated restructuring, upon which they staked their survival, and the capacity and incentive for industry investment in areas including pollution control declined.

Finally, the economic growth model used for this analysis is very useful to clarify the relationships between environmental pollution damages and economic growth in both developed and developing countries. In particular, the model could be expected to predict the interactions between health risks and economic growth in developing countries.

Acknowledgement

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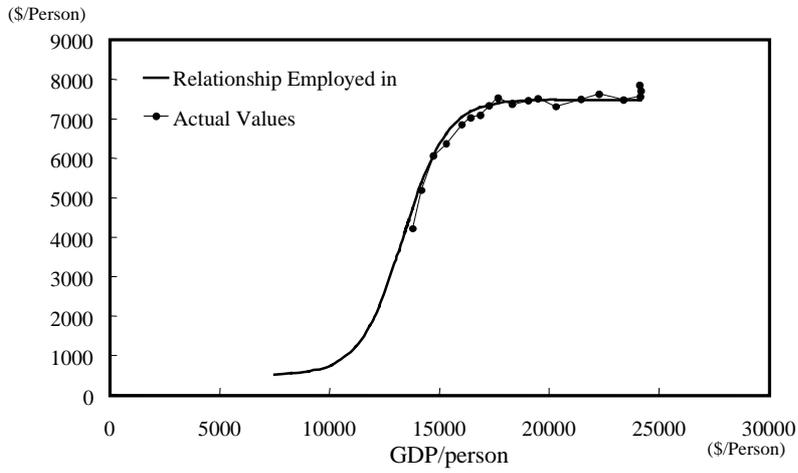


Figure 1 Relation Between Damages and GDP per Capita in Japan

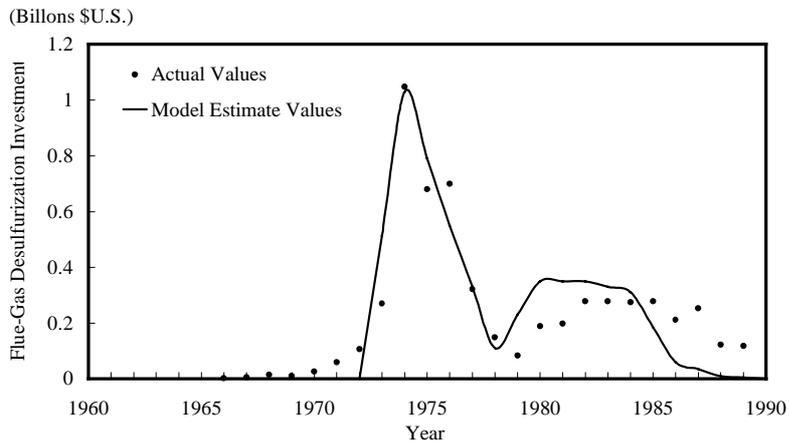


Figure 2 Actual Investments for Flue-Gas Desulfurization and Model Calculation Results (1960-1990)

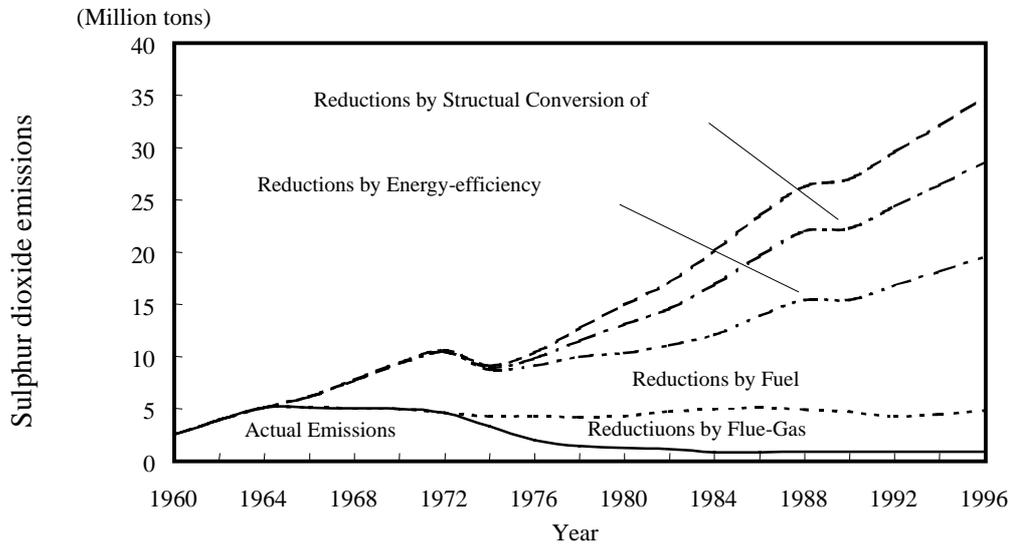


Figure 3 Factor Analysis of Sulfur Dioxide Emissions Reduction in Japan

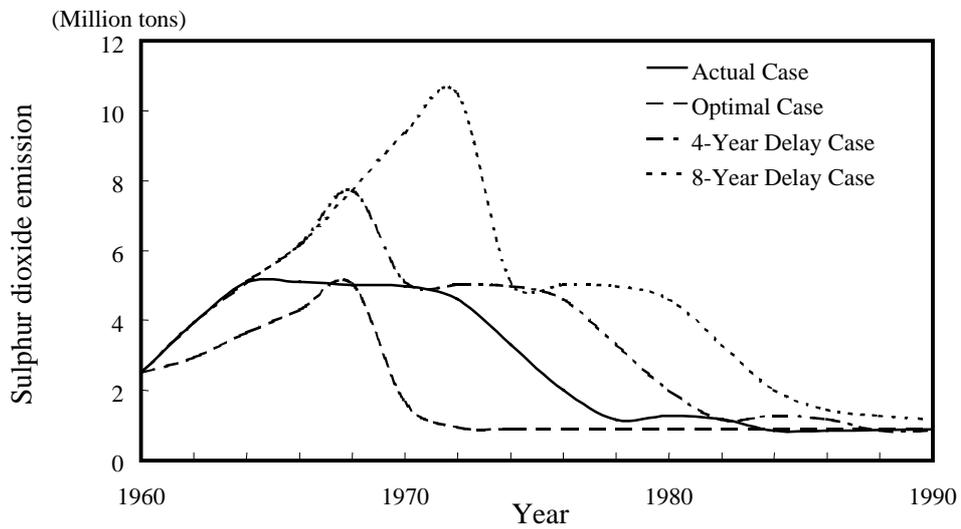


Figure 4 Sulfur Dioxide Emissions with Different Timing of Response

Flue-gas Desulphurization on Investment

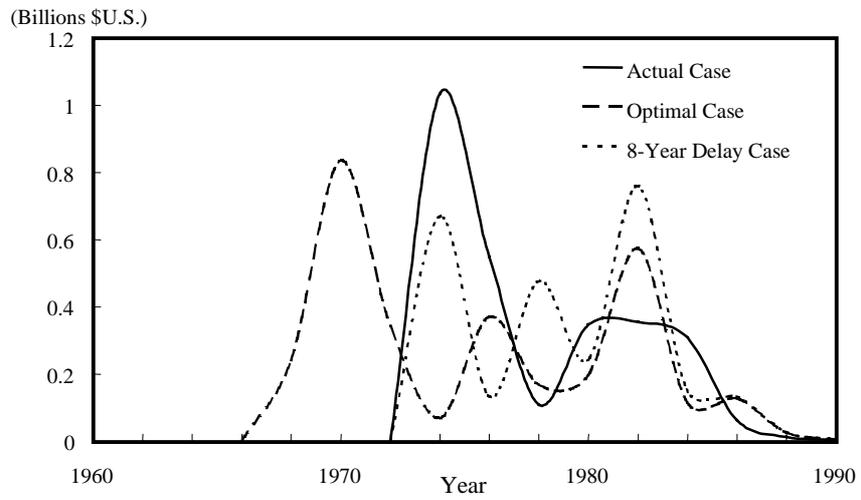


Figure 5 Flue-Gas Desulfurization Investment with Different Timing of Response

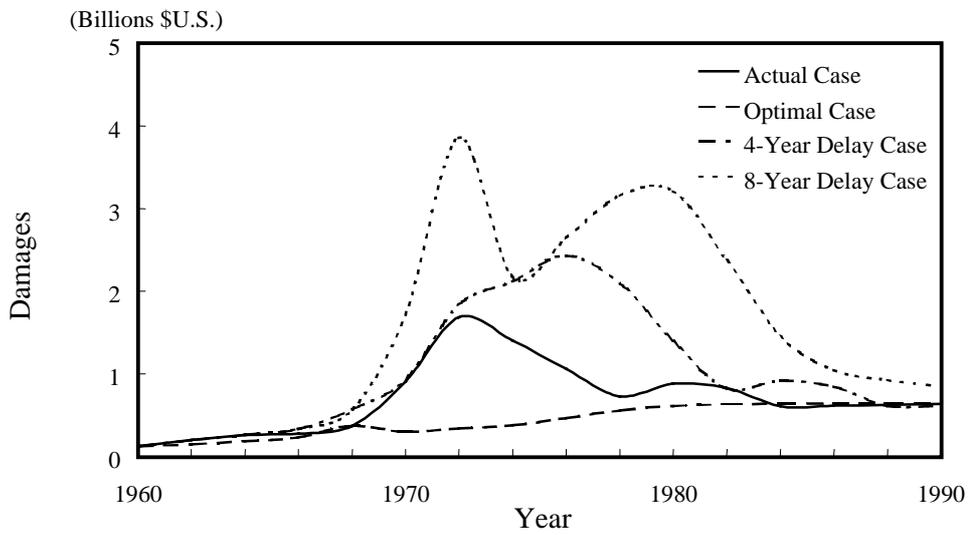


Figure 6 Damages with Different Timing of Response

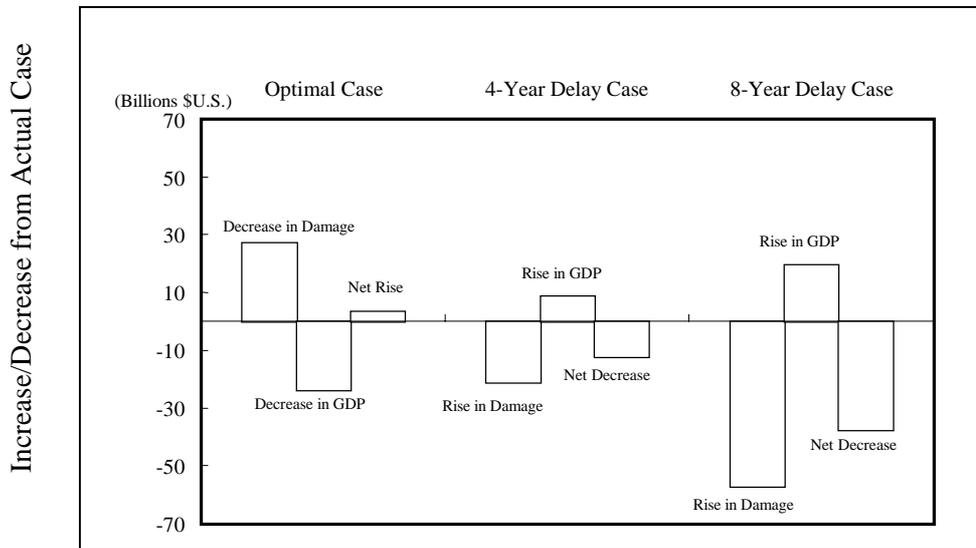


Figure 7: Damages and GDP Variation with Different Timing of Response

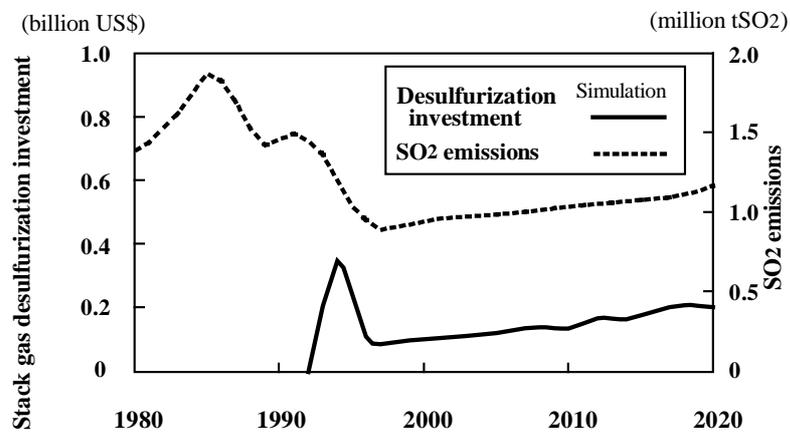


Figure 8: A Desulfurization Simulation for Korea

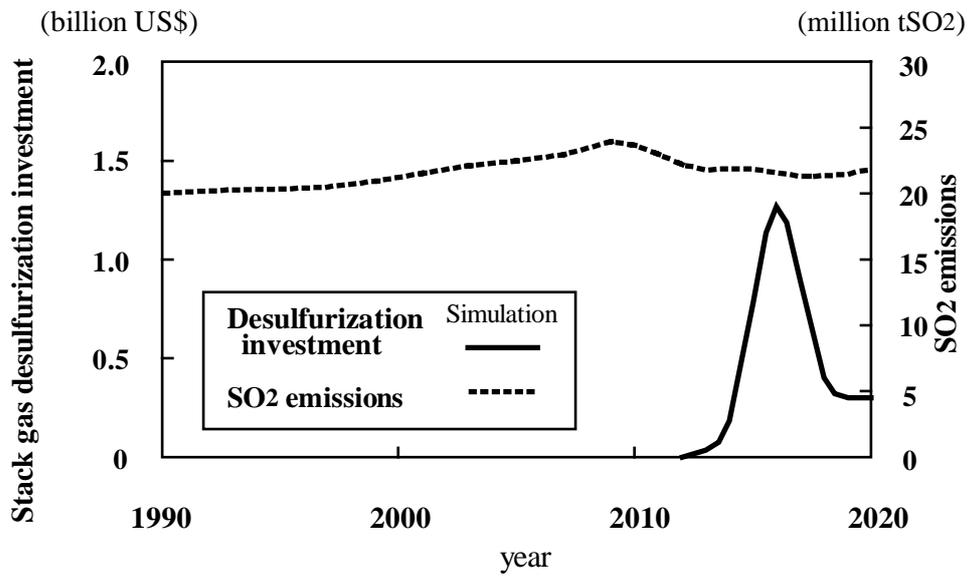


Figure 9 A Desulfurization Simulation for China

Case Study on Short Chain Length Chlorinated Paraffins

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Abstract

Short chain length chlorinated paraffins (SCCPs) are being assessed under Europe's Existing Substances Regulations. A risk assessment identified that the formulation and use of SCCPs in metalworking fluids poses risks to the aquatic environment and an outline risk reduction strategy identified four possible options for control. This paper discusses the issues raised by a risk-benefit analysis (RBA) of these control options. The analysis was undertaken in two stages with a qualitative assessment followed by a semi-quantified assessment.

Consultation was the main source of data for the analysis, with useful information provided by around 70% of the 200 consultees. While a reasonable amount of data were provided on the use and benefits of SCCPs in metalworking fluids, data on substitutes were minimal. Available data allowed quantification of some of the costs to industry arising from implementing control options. It was not possible, however, to value changes in environmental and human health costs and benefits.

The RBA was able to identify a preferred risk management option and to recommend that the option be tailored to achieve the appropriate balance between protection of the environment and the benefits of derogated use. The analysts believe that the RBA was fundamental in determining the most cost-effective risk management option. However, for its usefulness to be maximised, the risk management process needs to be fully integrated.

Background

Short chain length chlorinated paraffins (SCCPs) are hydrocarbons of chain length C₁₀ to C₁₃ inclusive, chlorinated in excess of 48%. SCCPs are used as extreme pressure additives in metalworking fluids, as flame retardants in rubbers and textiles, and in sealants, leather processing and paints and coatings.

In 1995, PARCOM (the Paris Commission) agreed to phase out the use of SCCPs by the year 2000 on the basis that these are persistent, toxic and bioaccumulative (PARCOM Decision 95/1). The PARCOM Decision is to be implemented by all parties to the Paris Convention, which are the thirteen countries bordering the North Sea and the northeast Atlantic (Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden and the UK) and the European Union (EU) as a whole.

SCCPs are also being assessed under Europe's Existing Substances Regulation (EEC 793/93). Under this Regulation, manufacturers or producers of existing substances are required to provide information to the European Commission (EC) on substances which are included on the European Inventory of Existing Commercial Substances (EINECS). This includes, for example, information on expected use, toxicity and exposure rates. On the basis of this information, priority lists are drawn up by

Member States and the EU which identify substances considered to require immediate attention due to their potential adverse effects on human health and/or the environment.

Each priority substance is assigned to a Member State which is responsible for undertaking an assessment of the risks associated with the substance.² Where the risks to the environment and/or human health are found to be too high, then the Member State (the rapporteur) is required to develop a risk reduction strategy.³

The UK is the rapporteur for the assessment of SCCPs. The risk assessment concluded that risks to human health arising from the production, formulation and use of SCCPs are acceptable. However, the formulation and use of SCCPs in metalworking and leather processing were found to pose risks to the aquatic environment which are sufficiently high to require reduction. An outline risk reduction strategy for the use of SCCPs in metalworking identified four possible options for control: marketing and use restrictions; classification and labelling; a voluntary agreement; and limit values on emissions. These options were assessed by Risk & Policy Analysts Limited (RPA) using risk-benefit analysis (RBA).⁴

RBA provides a framework for weighing up the advantages and disadvantages of alternative choices with the aim of ensuring that equal consideration is given to private sector costs and benefits and to environmental and human health risks, costs and benefits. An RBA can be undertaken at three different levels:

- 1) a qualitative analysis, where the risks and benefits of each option can be described, but are not quantified;
- 2) a semi-quantitative, semi-qualitative analysis, where the impacts of each option can be described but only some are quantified or valued in monetary terms; or
- 3) a cost-benefit analysis, where all of the identified costs and benefits are quantified and valued in monetary terms.

The RBA on SCCPs was undertaken in two stages: a qualitative analysis followed by a semi-quantitative, semi-qualitative analysis. The qualitative analysis was used to screen out options which would not achieve the necessary risk reduction, while quantification was used to identify the most cost-effective of the two remaining options.

The first stage of the study was commissioned at the end of January 1996 for completion within six weeks. A Stage 1 report was produced at the beginning of March and led to the commissioning of the second stage of work which began in mid-March. A Draft Final Report was produced at the beginning of June, at which time 90% of the work had been completed. Due to delays arising from consultation with industry, the Final Report for the study was not produced until January 1997. The two-stage study involved three analysts and was completed in just under 100 person-days. The most time-consuming element of the analysis was identifying and contacting relevant organisations, which took between three to four weeks. Data analysis took between four and five weeks in total for both the qualitative and quantitative assessments.

² Using the approach set out in *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 of Existing Substances*.

³ Using the approach set out in *Technical Guidance Document on Development of Risk Reduction Strategies*, October 1997 (revised version).

⁴ This paper deals only with SCCPs in metalworking fluids, although RBA was also used to identify the preferred risk control option for leather processing.

The RBA identified a ban on the use of SCCPs with derogations for some uses as the preferred risk reduction option. Further work on derogations was commissioned in August 1997. This has involved three analysts a total of 50 person-days and is due to be completed by the end of 1997.

Description of Socio-Economic Analysis

The Collation of Data for the Assessment

Data were gathered through both a literature review and extensive postal, telephone and face-to-face consultations with a wide range of UK and EU stakeholders, including all those in the chain of trade. Over 200 organisations were contacted in total, including:

- 28 companies involved in the production of SCCPs and other additives and the formulation of metalworking fluids;
- 59 large, medium and small users of metalworking fluids (plus an unknown number of anonymous users contacted via trade associations);
- 19 producers of metalworking machines and tools;
- 25 UK-based and 10 other EU-based trade associations;
- UK government departments and environmental regulators;
- relevant government departments and Competent Authorities in other EU Member States;
- UK water and waste disposal companies and similar organisations in other Member States;
- academics and research organisations; and
- the United States Environmental Protection Agency (US EPA).

As with other similar studies, consultation proved to be the source of the vast majority of data used for the analysis. Useful data were provided by around 70% of consultees, with important information being provided by: SCCPs manufacturers and their trade associations (providing data on sales of SCCPs and the hazards associated with alternatives to SCCPs); formulators and their trade associations (providing data on metalworking fluids in terms of their nature, benefits, sales and costs and data on alternatives to SCCPs in terms of their nature, product development and advantages and disadvantages); German industry and associated trade associations (data on processes which require the use of SCCPs); and some Governments such as the US (whose EPA provided reports arising from its own regulatory review of chlorinated paraffins⁵) and Denmark.⁶

⁵ For example, *RM2 Exit Briefing on Chlorinated Paraffins and Olefins*, December 1993.

⁶ For example, *Environmental Evaluation and Substitution Analysis - Cutting Fluids*, 1994.

The Risk Reduction Options

The gathered data enabled a qualitative analysis of the following four options, and rejection of the first two of these on the grounds that they would not be able to achieve the required level of risk reduction:

- voluntary agreement: based on an agreement by Euro Chlor (the European Chlorine Manufacturers Association) to phase out the use of SCCPs in metalworking by the year 2000. This would strengthen commitments already made by individual Euro Chlor members;
- classification and labelling: labelling of SCCPs as “dangerous for the environment” to encourage responsible handling and use;
- marketing and use restrictions: a ban on the use of SCCPs across the EU under the marketing and use Directive (76/769/EEC); and
- limit values on emissions: reducing emissions of SCCPs to below the level of concern using limit values and/or environmental quality objectives under Directive 76/464/EEC, which provides the framework for controlling discharges to the aquatic environment.

Data Gathered for the Assessment

The RBA required data on the use and benefits of SCCPs and the nature, availability and costs (including risks⁷) of alternatives. For the use and benefits of SCCPs, a reasonable amount of data were provided by SCCP producers and metalworking fluid formulators. In contrast, very few data were provided by users of metalworking fluids, with many users being unaware of whether or not they actually used SCCPs. Data on SCCP substitutes, and thus their associated risks, were minimal. This was due, in part, to their state of development and nearness to the market.

The assessment made use of four types of data:

- qualitative descriptions of costs and benefits: for example, information on the range of benefits provided by SCCPs and the types of costs which would arise from the use of less efficacious alternatives;
- trade and other statistics formally collected by government and industry: for example, data on sales of SCCPs and metalworking fluids for each EU Member State and data on reductions in the use of SCCPs for some Member States;
- commercial databases: for example, the Kompass database was interrogated to establish the number of metalworking companies in the UK and EU as a whole; and
- unpublished and unsubstantiated data (i.e. anecdotal data): for example, an estimate of the percentage of metalworking fluids containing SCCPs in the UK and an estimate of the percentage of metalworking processes for which alternatives to SCCPs are available.

⁷ RBA requires that the reduction in environmental and human health risks arising from a ban on the use of substance is compared with the increased risks associated with the use of alternatives.

Quantification of Costs and Benefits

The implementation of marketing and use restrictions would result in a move away from SCCPs to longer chain length chlorinated paraffins or to chlorine free fluids. Data allowed estimates to be made of the annual costs incurred as a result of the increased fluid prices arising from this move. It was also possible to make estimates of the relative importance of other costs arising from a ban on the use of SCCPs under the marketing and use Directive. Data were not available to allow an estimate of the costs associated with the limit value option. For both options, a lack of data on “stock at risk” (i.e. the actual impacts of SCCPs in the aquatic environment) meant that it was not possible to value the environmental benefits associated with reductions in the risks associated with SCCPs. Similarly, data on the impacts of SCCPs on human health were also poor, preventing valuation of changes in human health risks.

As with any such analysis, data were incomplete and it was necessary to use a number of assumptions to value impacts. The method used to value the annual costs associated with an increase in fluid prices in three EU Member States is set out in Box 1. The approach was chosen to minimise the number of assumptions and to provide a conservative estimate of costs (i.e. to ensure that costs were not underestimated).

An increase in fluid prices was only one of the costs arising from a move away from the use of SCCPs, with others including reductions in tool life, increases in machine down time, reductions in product quality and reductions in production rate. It was not possible to provide estimates of these other costs, as data were not available on the wide range of processes and large number of alloys in which SCCPs are used. However, using data on the costs of new metalworking tools and the costs of re-grinds it was possible to show that even small reductions in tool life (of the order of 5% to 10%) could result in costs which would exceed those arising from increased fluid costs.

Key Issues

The depth of the analysis was constrained by the initial short timescale of the study in that consultees could not respond in time for reporting. Indeed, some made the decision to provide no data on the basis that the timescale of the study was “impossibly” short.⁸ A longer timescale may have allowed further quantification of costs to industry associated with the marketing and use option. (That said, the degree of quantification would still have been hampered by the diverse nature of the industry.) Furthermore, the timescale of the assessment did not impact the analysts’ ability to value impacts on the environment and human health, which was constrained only by a lack of data on stock at risk.

As indicated above, quantification of the costs associated with the limit value option was not possible. As a first step to estimating these costs, the analysts examined the risk assessment assumptions to identify the number of facilities which may be required to reduce their discharges under this option. The risk assessment was unable to assist in this regard, due, in part, to the adoption of a realistic worst case approach to assessment (as required by the technical guidance document - see footnote 1). That said, sensitivity analysis of the risk assessment assumptions identified a range of users which may not be impacted by the limit value option (i.e. a number of users which posed “acceptable” risks to the environment).

⁸ As indicated above, the qualitative analysis was completed within six weeks of the commencement of the study, during which time consultees were identified and contacted, and a draft and final report prepared. As a result, some consultees had less than three weeks to respond to initial data requests.

Box 1: Increases in Fluid Costs Arising from a Ban on SCCPs

Background Information: Overall, 90% of EU sales of metalworking fluids are associated with just four countries: Germany; France; Italy; and the UK (which represent 32%, 25%, 20% and 13% of sales respectively). These four countries also represent 90% of SCCP sales, with the UK, France, Italy and Germany representing 32%, 30%, 15% and 13% of SCCP sales respectively.

Metalworking fluids containing SCCPs are either neat oils or emulsions. Neat oils are supplied ready for use directly with metalworking machinery and are composed of mineral oil containing a variety of additives such as corrosion inhibitors and anti-oxidants. Emulsions are soluble oils supplied as a concentrate containing biocides, corrosion inhibitors and other additives which, before use, are mixed with water to form an emulsion.

The average cost of metalworking fluids is £1.75 per litre. A move to medium chain length chlorinated paraffins (MCCPs - chain length C₁₄ to C₁₇ inclusive) would increase fluid costs by 5%. A move to chlorine-free metalworking fluids would increase fluid costs by around £0.50 per litre (or just under 30%).

The UK: Anecdotal reports indicate that in the UK 80% of SCCPs are used in neat oils while only 20% are used in emulsions. In 1995, UK sales of neat oils were 21,700t, sales of emulsion concentrate 10,950t and sales of SCCPs 2,740t. Assuming that there is a direct relationship between sales of metalworking fluids and sales of SCCPs, that 80% of SCCPs are used in neat oils and that the average concentration of SCCPs in the neat oil is 10% indicates that all neat oils contain SCCPs. Similarly, assuming that 20% of SCCPs are used in emulsion concentrate and that the average concentration of SCCPs in the concentrate is 15% indicates that 3,650t (or 33%) of emulsions contain SCCPs.

If all neat oils sold in the UK contain SCCPs, then a move to MCCPs would result in increased metalworking fluid costs of around £2 million per annum. In contrast, a move to chlorine-free EP additives could result in increased neat oil costs of around £11 million per annum. For emulsions, if only 35% of emulsion concentrate sold in the UK contains SCCPs, then a move to MCCPs would result in increased metalworking fluid costs of around £335,000 per annum. As for neat oils, the move to chlorine-free EP additives would increase costs to around £2 million per annum for emulsion concentrates.

Germany: In Germany, the use of chlorinated paraffins in metalworking fluids is only 10% of 1987 levels. If it is assumed that in 1987 all metalworking fluids were based on the use of SCCPs and that all chlorinated paraffins which are currently used are short-chained, then 7,775t of the 77,750t sold in Germany will contain SCCPs. Assuming that fluid costs in Germany are on a par with those in the UK and that the increases in costs associated with a move away from the use of SCCPs will also mirror those in the UK, then a move to MCCPs would result in increased fluid costs of around £675,000. A move to chlorine-free fluids would result in increased fluid costs of around £4 million.

France: In France, SCCP-based fluids represent approximately 10% of metalworking fluid consumption. Thus, 5,980t of the 59,800t of metalworking fluids sold in France contain SCCPs. Assuming that fluid costs and associated increases will be on a par with those in the UK, a move to MCCPs would result in increased fluid costs of around £525,000. A move to chlorine-free fluids would result in increased fluid costs of around £3 million.

This sensitivity analysis was not viewed favourably by some EU Member States, on the basis that the risk assessment had been agreed by the EC (its assumptions therefore not being up for question). Had it been possible to develop estimates of the costs of the limit value option, the indications are that the associated assumptions would have conflicted with those of the risk assessment. Any such differences are obviously not ideal in the wider context of developing strategies for controlling hazardous substances.

Most of the data used in the assessment were associated with the first and fourth of these categories and were included in the assessment as “pers. comm.” (i.e. the source of the data was not disclosed in line with the wishes of the consultees). As may be expected, there were conflicting views within industry as to the substitutability of SCCPs and over which substitutes would be adopted for different processes and metals.

Description of How the Socio-Economic Analysis Was Used

The RBA identified marketing and use restrictions under Directive 76/679/EEC as the preferred risk reduction option. More specifically, the RBA recommended a ban on the use of SCCPs with:

- technical or financial derogations where a move away from SCCPs may compromise the viability of metalworking companies, with this being contingent on the benefiting company taking steps to ensure that discharges to the environment are minimised; or
- derogations where chlorine-free replacements for SCCPs pose greater risks to the environment or human health than SCCPs themselves.

In both cases, the need for derogations was based on limited qualitative information and further work was recommended to further validate derogated uses.

The RBA and subsequent work (described below) have been used to make recommendations to the EC concerning risk reduction for SCCPs. These recommendations were approved by an *ad hoc* EU group working on risk reduction strategies in November 1997, and are to be formally considered by the EC at the beginning of 1998.

Further (on-going) work on derogations enabled a reduction in the number of derogations for technical or financial reasons⁹ and identified a third category of derogation arising from regulatory or contractual constraints on the use of metalworking fluids.¹⁰ This additional work has been useful targeting derogations and thus in assisting in the adoption of recommendations by the EC. More generally, there are three other factors which have maximised the acceptability of the RBA and its findings. Firstly, the analysis is transparent with all assumptions clearly set out. Secondly, before finalisation, comments on the study were received from UK industry, in particular a UK-based manufacturer of SCCPs and the UK trade association representing metalworking formulators (British Lubricants Federation). While it was not appropriate to address all comments made, this level of consultation has ensured that the study has a sound factual basis. (On the downside, this commenting process took almost twice as long as the analysis to complete.)

⁹ The original RBA suggested that perhaps nine processes, representing up to 20% of SCCP use, may require derogation from a ban. None of these processes now appears to require derogation.

¹⁰ This work was assisted by a survey undertaken by the UK trade association representing metalworking formulators (British Lubricants Federation) which identified candidate processes for derogation. Useful information was also available from Germany, where national legislation has resulted in a move away from the use of SCCPs in most metalworking processes, SCCP use being concentrated in those processes requiring SCCPs.

Finally, the two-stage assessment process, and in particular the use of a qualitative assessment followed by a quantitative assessment, is believed to have improved the quality and thus acceptability of the analysis. The qualitative assessment allowed options which would be unable to achieve the required level of risk reduction to be discarded and for the quantitative assessment to focus on appropriate options. Quantification was believed to be necessary, as the conclusions of the qualitative RBA were open to criticism on the grounds of subjectivity and a lack of hard evidence. The semi-quantitative analysis provided a more objective basis for decision making and assisted in focusing the discussion of advantages and disadvantages. In general terms, it is believed that the greater the level of quantification achieved, the more likely it is that the analysis will be robust in its conclusions and provide a sound basis for considering the trade-offs associated with different risk reduction options.

Lessons Learned

Overall, the analysts believe that the RBA of SCCPs was successful in that it identified the preferred risk management option from a range of options and also enabled this option to be tailored to minimise environmental and human health risks and costs to industry.

The fact that the original RBA had a short timescale did impact data gathering. However, it is believed that this did not impact the study conclusions. While more time would have allowed additional data gathering in some areas, this is not the case for all data. For example, detailed data on the full range of substitutes for SCCPs are not available even now, and it is often the case that analyses need to be structured to deal with limited data on substitutes. Given the short timescale of the study, additional work to identify derogations from a ban on the use of SCCPs was essential for the specification of the preferred risk management option. Indeed, still more work is needed in this area and will be undertaken by the EC if recommendations for action are adopted in 1998.

In hindsight, the delay between the original RBA and the study on derogations was beneficial in that it provided an impetus for industry to think seriously about the need for derogations. In addition, the changes which had taken place in the industry in the 14 months between data gathering for the RBA and the new work on derogations gave the analysts the opportunity to re-examine some of the data and assumptions used in the initial analysis and re-confirm their validity. A further review of the analysis may also be an indirect outcome of future work to be undertaken by the EC.

As a result of experiences on this and other projects, the analysts believe that the following are the critical features of an effective analysis for use in decision making:

- the analysis should consider the full range of impacts arising from a risk reduction option and must consider substitute chemicals if the option would result in their use;
- the analysis should be based on on-going consultation with key players, with which it may be possible to reach some form of consensus, but without which consensus is unlikely;
- the analyst should collect sufficient information to gain a good understanding of why and how the chemical is used: without this, it is difficult to ensure that the full range of costs and benefits of a given control option are identified;
- the analysis should be quantitative where possible: it is believed that quantification always helps the analysis by making it more objective and by providing a focus for discussion of trade-offs;
- the analysis should be clear and easy to understand, and assumptions and trade-offs should be made explicit;

- if more work is necessary to specify a risk management option, then this should be undertaken; and
- With respect to consultation, this should be continuous throughout the entire risk management process. In the EU, risk assessment and the development of risk reduction strategies are separate procedures and involve separate consultation exercises. The analysts believe that the development and implementation of risk reduction strategies would benefit from a continuity of consultation, with key players being informed of progress with decision making and any new data requirements.

The Use of Economic Analysis to Enhance Voluntary Risk Management Decision Making

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Introduction

The mission of the United States Environmental Protection Agency (EPA) is to protect human health and the environment. Traditionally, the EPA has fulfilled this responsibility by using regulatory tools designed to prescribe how such protection should be accomplished. The EPA has also participated, with business and other stakeholders, in voluntary projects that allow mutual goals of environmental protection to be met and that extend the EPA's resources. Many of these projects are part of the EPA's Design for the Environment (DfE) Program. Through Agency and stakeholder collaboration, DfE helps businesses to analyse the risks associated with the use and manufacture of chemicals and encourage their consideration along with other business decision making factors.

The DfE projects have drawn interest and significant participation from the private sector. Business's interest in participating in these voluntary projects stems from its desire to meet environmental protection goals flexibly, without unduly constraining the ability to meet the overall goals of the business. This is particularly important because the EPA and businesses generally emphasize different factors when making chemical risk management choices.

This paper describes a tool the DfE Program uses to support businesses in making environmentally sound choices and focuses on how economics is used as part of that tool. It first describes the differences in perspectives on the impacts of decision making between businesses and the public sector. These differences help explain why some environmental considerations may not be incorporated into private decision making. Following, the paper describes a DfE tool developed to assist businesses to incorporate these considerations. The discussion focuses on how economic analysis is used as part of this tool. This is followed by a brief illustration featuring an example from a DfE project.

Social vs. Private Perspectives

Public agencies, such as the EPA, are concerned with the social costs and benefits of decisions. Social costs are the costs that an action imposes upon society and include both the costs to those directly affected by the decision, often termed private costs, and the external costs to others who are not directly affected by the decision. External costs can include effects on public health and the environment. Social benefits can be described as both those benefits resulting directly from a decision and those benefits accruing to parties external to the requirements of the decision.

Alternatively, business decisions are generally made based on the private implications of the decision, those that affect the costs and profitability of the enterprise. Therefore, businesses may not recognize the external implications of their decisions. The rationale behind this decision methodology can be traced, in part, to a firm's profit maximizing behaviour; profits are generally unaffected by external costs and benefits. Businesses, too, often lack knowledge of the external effects of their decisions, and thus are unable to consider them. Many small businesses, for instance, simply do not have the resources to develop information on external effects, or be aware that they exist. Figure 1 depicts how a business

decision may have private and external effects. Sometimes external effects are overlooked, and therefore businesses may not consider the full social implications (private and external effects) of their decisions. Sometimes it is possible for external effects to be manifested as private effects. An example is the liability costs faced by a business that result from contamination of a groundwater source resulting from improper disposal of toxic chemicals. These types of costs may or may not be recognized by the business decision maker, although they can directly affect profitability. The DfE program focuses on developing information on both the private and external effects of business decisions, promoting an understanding of how the external effects, in particular, affect both profitability and social welfare.

Design for the Environment’s Cleaner Technologies Substitutes Assessment

As noted previously, small businesses often do not have the resources to enable them to assess all of the implications of their decisions. One of the goals of the DfE Program is to work collaboratively with these businesses, trade associations, public interest groups, academia, and others to incorporate environmental considerations into the design and redesign of products, processes, and technical and management systems. The DfE Program often uses a tool known as a Cleaner Technologies Substitute Assessment (CTSA). The CTSA uses concepts of cost-benefit analysis to present information in a convenient format.

The CTSA serves as a repository for information and makes no conclusions about the choices that businesses should make. It is an enabling document that provides information and approaches that allow businesses to incorporate environmental considerations in a way that is most appropriate to individual circumstances.

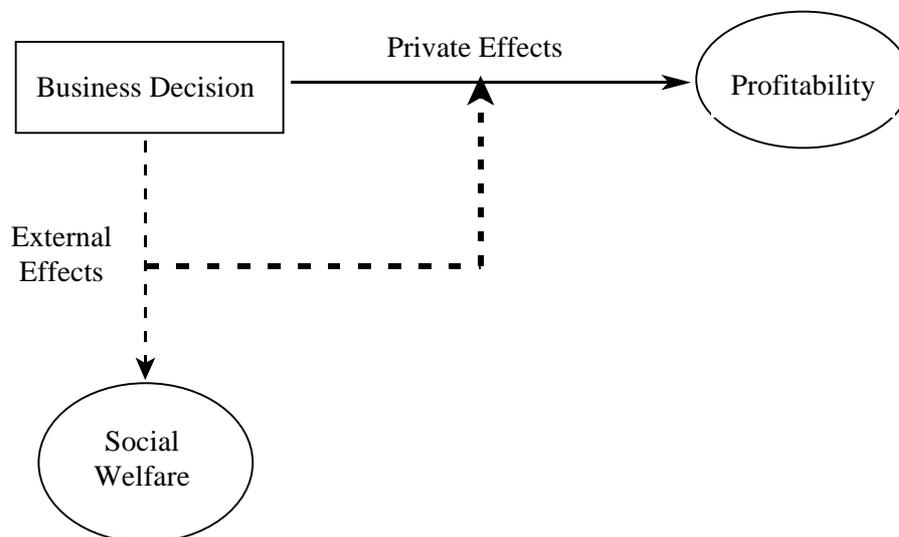


Figure 1. Relationship of the business decision to private and external effects. The business decision maker may not consider the external effects of the decision on social welfare (depicted by the dashed line). These external effects may be considered to the extent that they become private effects and impact profitability.

Economic Analysis and the CTSA Approach

The CTSA approach is to provide information on the private and external effects of technology choices. Technologies that can substitute for each other are selected for analysis. Information is then developed comparing the substitutes with a baseline technology using techniques including social cost-benefit analysis.

The goals of the social cost-benefit analysis in the CTSA are:

- Describe expected private and external benefits of the alternatives relative to the baseline, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefit;
- Describe expected private and external costs of the alternatives relative to the baseline, including any adverse effects that cannot be quantified in monetary terms and the identification of those likely to bear the costs; and
- Determine the potential net benefits (benefits minus costs) of the alternatives as compared with the baseline, including an evaluation of effects that cannot be quantified in monetary terms (US EPA 1996).

Developing this information typically involves the same steps that would be included in an analysis of the costs and benefits of public policy. They include defining the baseline technology and evaluating the changes in social costs and benefits that result from substituting an alternative technology. This process necessarily involves the collection or development of information on the technologies, including market analysis, technology descriptions, assessment of risks (hazards and exposure), and competitiveness and conservation analyses.

The market analysis, primarily an economic assessment, is useful for characterizing the industry. Along with an overview of technologies, the market analysis can help to define the limits of the project. The CTSA's risk assessment might include "information on environmental releases and transfers of pollutants, chemical exposure levels, and health and environmental risks from toxic chemical exposure. These are often the external effects of technology choices that DfE hopes to introduce. The CTSA also provides analysis of conservation factors, including "energy impacts and effects on resource conservation" (US EPA 1996). Additional information provided in the CTSA includes process safety, regulatory status of chemicals or technologies, and costs, including capital and labour expenditures (US EPA 1996).

Data for the CTSA are collected and/or developed from a variety of sources; stakeholder involvement is often substantial. Information may come from chemical manufacturers, suppliers, trade associations, public-interest groups, or might be contributed by educational institutions or the EPA itself. The collaborative nature of the CTSA generally results in the development of better information than small businesses would generally be able to develop on their own.

Ultimately, the information developed in the CTSA is arrayed in a social cost-benefit framework to aid comparison of baseline and substitute technologies. To the extent possible, social benefits are monetized to facilitate comparisons with social costs. Table 1 depicts a general example of the types of costs and benefits that might be evaluated for a baseline technology and one alternative, and shows how they might be presented. In the table, benefits and costs are identified as private and external. The comparison highlights the importance of considering external effects. An effect, such as an odor outside a plant, that results from choosing the baseline technology could be overlooked. However, the alternative technology may not produce an odor and may increase goodwill in the community. This increase could translate into a consumer's willingness to purchase that business's product. Here, the external effects of a technology choice (choosing an alternative without an odor) could translate into private effects (increased

goodwill and sales). The comparison of technologies in the cost-benefit framework will highlight these results.

As with any social cost-benefit analysis, it is likely that many costs and benefits cannot be monetized or even quantified. The assessment, however, should identify qualitative factors to ensure that they can be considered by the decision maker. Table 1 provides a qualitative description of the costs and benefits, for example “Leaks could contaminate groundwater”, that could be used to supplement the typical unit comparison (e.g., \$, level, etc.) (US EPA 1996).

The DfE Program has developed several CTSA's used to support business decision making. To illustrate use of economic analysis in the CTSA, this paper uses the draft *Printed Wiring Board Cleaner Technologies Substitutes Assessment: Making Holes Conductive* (US EPA 1997, Draft).

Printed Wiring Boards

“The printed wiring board (PWB) is the underlying link between semiconductors, computer chips, and other electronic components” and is a key component in many high technology industries. However, the traditional manufacturing process for these boards uses chemicals that may pose hazards to human health and the environment, creates hazardous waste, and uses large amounts of water and energy. While the industry is interested in exploring alternative technologies that may reduce pollution and benefit the environment, it is also characterized by small businesses that are not able to develop information needed to evaluate technologies (US EPA 1997, Draft). This scenario has the hallmark of an EPA DfE project: a project where the EPA can couple its resources with those of interested partners to develop information that helps inform the industry's technology choices.

One component of the PWB project sought to develop information useful for comparing seven technologies for “making holes conductive” (MHC), part of the PWB manufacturing process. In a process similar to the one used to develop information to support the regulatory decision making process, economic information was gathered on the market for printed wiring boards and costs for alternative technologies. In addition, information was developed detailing process descriptions, chemistry, risk (including chemical releases, human health and ecological hazard, and exposure), process safety, performance, regulatory requirements, energy requirements, and pollution prevention practices. This information was developed with significant input and interaction by peer reviewers.

Economic Support

The project initially developed general economic information on PWBs, including the types of processes, market for PWBs, types of manufacturers, and employment numbers. This resulted in development of a profile of the PWB use-cluster, a group of chemicals or technologies that can substitute for one another, and aided in narrowing the focus of the project to seven MHC technologies. The information developed on markets, including international competitiveness, and employment was used later when comparing effects of choosing the various technologies.

A basic cost analysis provided information on the private costs of the seven MHC alternatives. Costs were developed for each of the MHC processes and equipment configurations (US EPA 1997, Draft). Categories of costs included capital, operating and maintenance costs, and environmental costs, such as energy and water consumption and wastewater generation. Considered, but not quantified, were costs related to wastewater treatment and solid waste disposal. All costs were developed for a standard job size, then compared with costs of that job for a baseline technology. The baseline technology was selected due to its prevalence in the industry and concerns for risk and resource use. The cost analysis helped identify which component of cost was most significant for these technologies (generally chemical cost), and indicated that all of the technology substitutes evaluated were more cost-effective than the baseline

process (US EPA 1997, Draft). While important for comparing technologies, cost is not the only consideration.

Table 1. Types of Costs and Benefits That Might Be Evaluated for a Baseline Technology and One Alternative, and How They Might Be Presented

Type	Typical Unit	Sample Comparison Total Value (+,-,\$)	
			Alternative 1
Benefits			
<i>Private</i>			
Employee productivity	\$	Employees may be absent or ill on the job	Fewer absences and more productive on the job
Odor within a plant	Level (H,M,L)		
Product quality	\$, Level (H,M,L)	Results in superior quality product	Inferior quality could lead to reduced sales
“Green” marketability	\$ (e.g., revenue from “environmentally conscious customers”)		May be able to sell to new customers, or charge a higher price
<i>External</i>			
Health risks to workers	Worker lives saved, reduced cases of illness, \$	Employees likely to be ill, increased health care costs	Workers less likely to suffer from illness, decreased health care
Odor outside plant	Level (H,M,L)	Complaints from community	Gain “goodwill” of community
Ambient water quality	Concentration, effect, description (e.g., cloudy)	Potential source of reduced aquatic populations (fish stocks)	Possible increase in aquatic populations, e.g., leading to increased fishing
Landfill contamination	Level (H,M,L), \$	Leaks could contaminate groundwater	None
Costs			
<i>Private</i>			
Capital	\$		Must purchase new machinery
Hazardous waste disposal	\$	Must pay to dispose of chemical	None
Operations	\$	Average costs	Higher than baseline
Energy costs	\$	High costs	Lower than baseline
Liability claims	\$ (Expected value of damages)	High legal fees and damages if contamination event occurs	None
<i>External</i>			
	Amount of particulate		New technology causes air emissions

Businesses traditionally consider the types of costs examined in the cost analysis when making technology choices, although some environmental costs evaluated (e.g., wastewater generation and treatment) may be overlooked unless they affect private costs. As previously stated, one important feature of the DfE Program is that it encourages industry to consider costs and benefits beyond the business's walls, that is, the external costs and benefits that are also of concern to the EPA. Therefore, for the analysis of MHC technologies, additional consideration was given to the external costs associated with health and environmental risks, resource use, and other factors. As depicted in Figure 1, a relationship often exists between external and private costs that may not be recognized by the decision maker.

For instance, occupational health effects were categorized as both private and public costs. The cost-benefit analysis helps to show that the firm may experience reduced liability and insurance costs, and an increase in productivity (fewer days of work lost to illness) resulting from a technology choice other than the baseline (US EPA 1997, Draft). In addition, external costs related to the workers could include reduced costs to the worker for health care. To express the potential value of the external costs, estimates of the costs of some of the illnesses related to exposure to MHC chemicals were evaluated. Care was taken not to imply that these would be the actual benefits achieved by switching from the baseline to an alternative technology. Instead, this information was provided to support thoughtful decision making by showing that avoiding the subject ailments would benefit society (US EPA 1997, Draft). Sample estimates of willingness to pay for avoiding eye irritation and headache were estimated to range from \$21 to \$46 and \$2 to \$67, respectively (Unsworth and Neumann, 1993 as cited in US EPA 1997, Draft).

Table 2 presents the findings of the social cost-benefit analysis for the MHC technologies. This table aggregates information from most of the relevant decision factors, including cost, performance, risks, and conservation. Results are presented qualitatively because data limitations did not allow for monetization of all of the costs and benefits. However, the results still show that considerations beyond private costs, including external environmental effects, can affect decisions. For instance, it appears that all of the technologies cost less than the baseline technology. However, some technologies offer little, if any, improvement in worker and public health risks, aquatic toxicity, and energy consumption. Any of these factors could become significant factors in decision making, particularly if they result in private effects, such as increased liability, damage to company name and reputation, etc. The use of the social cost-benefit approach makes these concerns evident for the business maker and provides the same type of information that the public policy maker would examine.

The results of this CTSA have been widely disseminated to industry members to enable them to more adequately compare alternative MHC technologies. Through information sharing of this sort, the EPA hopes to encourage consideration of pollution prevention and risk management in the selection of MHC technologies. This allows the EPA to meet its environmental protection goals while giving the PWB industry flexibility in meeting its own needs.

Table 2. Relative Benefits and Costs of MHC Alternatives

MHC Technology	Production Costs (\$/ssf)	Number of Chemicals of Concern ^a			Water Consumption (gal/ssf)	Energy Consumption (Btu/ssf)	
		Worker Health Risks ^{b,c,d}		Public Health Risks			High Aquatic Toxicity Concern ^{b,c}
		Inhalation	Dermal	Inhalation			
Electroless Copper, non-conveyorized (BASELINE)	\$0.51	7	6	0 ^f	9	12	573
Electroless Copper, conveyorized	↘↘	↘↘	↔	↔ ^g	↔	↘↘	↘↘
Carbon, conveyorized	↘↘	↘↘	↘↘	↘	↔	↘↘	↔
Conductive Polymer, conveyorized	↘↘	↘↘	↘↘	↘	↘	↘↘	↘↘
Graphite, conveyorized	↘↘	↘↘	↘↘	↘	↔	↘↘	↘↘
Non-Formaldehyde Electroless Copper, non-conveyorized	↘	↘	↘	↘	↔	↘↘	↘↘
Organic-Palladium, non-conveyorized	↘↘	↘↘	↘↘	↘	↘	↘↘	↘↘
Organic-Palladium, conveyorized	↘↘	↘↘	↘↘	↘	↘	↘↘	↘↘
Tin-Palladium, non-conveyorized	↘↘	↘	↔	↘	↔	↘↘	↘↘
Tin-Palladium, conveyorized	↘↘	↘↘	↔	↘	↔	↘↘	↘↘

Source: US EPA, 1997. *Printed Wiring Board Cleaner Technologies Substitutes Assessment: Making Holes Conductive*. Volume 1. Draft. EPA 744-R-97-002a.

- a Does not include proprietary chemicals, which could include additional chemicals of concern.
 - b For technologies with more than one chemical supplier, all chemicals may not be present in any one product line.
 - c For the most exposed individual (e.g., an MHC line operator).
 - d Because the risk characterization did not estimate the number of incidences of adverse health outcomes, the amount of reduced risk benefit cannot be quantified. However, based on the level of formaldehyde risk and the number of chemicals of concern for the baseline, it appears all of the alternatives have at least some reduced risk benefits from the baseline.
 - e Technologies using copper sulfate were assigned a neutral benefit or cost; other technologies were assigned “some benefit” because none of their chemicals are as toxic to aquatic organisms as copper sulfate. This assessment is based on hazard, not risk.
 - f No chemical risks above concern levels. However, it should be noted that formaldehyde cancer risks as high as 1×10^{-7} were estimated.
 - g No chemical risks above concern levels. However, it should be noted that formaldehyde cancer risks as high as 3×10^{-7} were estimated.
- Key: ↔ neutral, less than 20 percent increase or decrease from baseline
 ↘ some benefit, 20-50 percent decrease from baseline
 ↘↘ greater benefit, 50 percent or greater decrease from baseline

Conclusion

The EPA has found that nonregulatory alternatives show promise in meeting its goal of protecting human health and the environment while allowing business to also meet environmental and business goals in a flexible manner. The incorporation of environmental considerations in business decision making requires identification and understanding of both the private and external effects of decisions. Therefore, the EPA has developed tools that assist businesses to recognize the totality of effects. The EPA's Design for the Environment Program has developed the Cleaner Technologies Substitutes Assessment to serve as a repository of information that businesses can use to evaluate the implications of their technology choices. The CTSA contains analysis of economic factors, such as markets and costs, as well as information including risks, legal considerations, energy and conservation issues, and performance of technologies. This information is placed in a cost-benefit framework to facilitate technology comparisons.

While technology decisions still lie with the business decision maker, the use of economic analysis within the context of the EPA's DfE Program brings to light the relevance of the external impacts of the business decision. Additionally, this type of analysis can also show why the external impacts of the business decision, particularly concerning health and the environment, can have repercussions for the business itself. It is hoped that armed with this type of information, as well as the approaches for developing it, businesses will make choices that provide environmental benefits to both the business and society as a whole.

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UK Health and Safety Executive Approach to Exposure Limit Setting

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United Kingdom

Introduction

The UK regulatory framework for Control of Substances Hazardous to Health (COSHH) includes two types of inhalation exposure limits. These are the Occupational Exposure Standard (OES) and the Maximum Exposure Limit (MEL). Broadly, an OES defines a limit of exposure, below which scientific consensus judges that ill-health should not arise. Where either the known dose-response relationship cannot identify a safe level of exposure, or where it is not reasonably practicable to control exposure to a safe level, a Maximum Exposure Limit (MEL) may be defined.

In UK law, an employer must prevent exposures from exceeding any MEL and must take all reasonably practicable measures to reduce exposure below the MEL. Since no safe level of exposure can be defined for substances that are considered for a MEL, the limit setting process is not dependent upon science alone, but is based upon socio-economic factors.

The paper discusses data acquisition aspects of Cost Benefit Analysis (CBA) to support setting a MEL and the part that CBAs play in the wider decision making process. Reference is made to particular studies to illustrate essential points and the relationship between the CBA and wider policy considerations.

Background

CBAs have been prepared for all new significant health and safety regulations since 1982. CBAs have been provided for individual MEL proposals since 1993. Previously, a CBA would only have been carried out on the overall regulatory package (COSHH).

The CBA forms part of the information considered by the Health and Safety Commission (HSC) when it decides whether to consult on a particular proposal. In the case of MELs, a CBA is produced early in the decision making process, for consideration by the HSC's Advisory Committee on Toxic Substances (ACTS).

The CBA, or a summary of its findings, is included in the Consultation Document. It may be revised if the proposals are amended following consultation, or if consultees' responses indicate that estimates of costs or benefits ought to be revised. The final CBA is part of the information submitted to Ministers when they are asked to approve legislation. All CBAs are available to the public on request.

In deciding whether to give the go ahead to a proposal, the HSC and Government Ministers will consider a range of factors and information. The CBA, which presents the expected socio-economic impact of a proposal in a structured way, is only one of these. It should be emphasised that CBAs are only an aid to decision makers. They do not provide a decision making rule.

Wider policy considerations are involved in the decision making process. For example:

- The severity of the **hazard**, i.e. the toxicological evidence and the degree of certainty particularly with regard to the health effects in humans;
- The severity of the **risk** including:
 - i. the number of workers exposed;
 - ii. the volume of substance usage;
 - iii. changing patterns of use - past, present and anticipated usage.
- Adequacy of current control including references to:
 - i. ill-health statistics and the available information on trends;
 - ii. the number and size of workplaces using the substances. For instance, if usage is limited to a few large companies then adequate in-house standards may already exist.
- European legislation (e.g. to implement EU Directives such as that setting limits for benzene);
- HSE's resources and the need to give higher priority to substances giving greater cause for concern;
- Prioritisation of substances may also reflect pressure group concern and representation.

Many substances may be judged to present a significant hazard and yet present a small risk if the substance is well controlled or the number of people exposed or the volume of usage is small. Low priority is given to limit setting for such substances. By way of example, a recent decision was taken not to proceed with a MEL for ethylene diamine (EDA) (see case study below).

Ill-health statistics are particularly difficult to gather either for substances which have a significant latency period for the onset of symptoms (e.g. for carcinogens such as aniline) or where symptoms can result from a variety of mechanisms which may not easily be related to the substance (e.g. asthma). Issues of underreporting and consistency of the database often preclude robust trend analysis.

CBA Data Requirements and Processes in Acquiring Data

HSE's Economic Advisers Unit and Occupational Hygiene Unit prepares CBAs for MEL proposals in very close consultation with policy divisions and other specialists (inspectors, engineers, statisticians, toxicologists and epidemiologists).

HSE seeks to identify best practice and then, through consultation with industry, estimates the cost of necessary control measures. Estimates then need to be grossed up and aggregated across a sector or range of sectors to estimate the total cost.

Where users are already failing to meet existing standards or limits, HSE takes the approach that the cost-benefit analysis should be based upon the standards that are current within the workplace and not upon the standards that ought to be in the workplace.

A wide range of internal and external sources of information may be used to prepare a CBA. CBAs are generally conducted to tight resource and time constraints. This means that large-scale data-gathering exercises purely for a CBA are neither practicable nor value for money. HSE therefore uses existing sources of information, which may have been collected at an earlier stage in the policy making

process. For example, the initial decision on whether an OES can be set for a substance is taken by the Working Group on the Assessment of Toxic Chemicals (WATCH) sub-committee of ACTS, on the basis of specialist toxicological advice. Much of the information on the health effects of the substance and some of the baseline information on numbers of firms and employees affected will already have been collected and set out in what is called a "Criteria Document". Such information also informs the judgement on when to proceed with the limit setting approach in the first instance.

However, dose-response relationships are often extremely difficult to obtain with any accuracy. Indeed it is often because of the absence of dose response relationships that an OES cannot be justified and the decision is taken to propose a MEL. Thus, estimates of the health benefits of controlling to lower exposures is often most uncertain.

Existing information is supplemented with small-scale and targeted enquiries to firms, trade associations and other stakeholders. These enquiries will focus on exposure situations at these organisations, what (if anything) further needs to be done to comply with the proposal, what this might cost and whether there are any operational benefits associated with these actions. All regulatory appraisals must explicitly consider the impact on small businesses, charities and the voluntary sector; hence the data collection exercise also includes a Small Firms Litmus Test designed to test for any particular implementation problems that small firms may face.

Costs

Responses from industry are critically assessed by HSE. For example, actions reported by firms to comply with the MEL are compared against exposure data and the level of exposure which would be expected from controls already in place. The costs of these actions will be cross-checked against other information, such as HSE's own estimates of the cost of Respiratory Protective Equipment (RPE). In some cases HSE will conclude that industry's own estimates are reasonably accurate. In other cases, HSE might consider that the estimates are on the high side (for example, industry may be able to comply with the proposal with relatively small-scale improvements to existing controls rather than new capital equipment) or on the low side (for example, costs of RPE may include the cost of purchasing the equipment but not the time needed to train staff in how to use it). In any case, HSE will report industry's own estimates, present its own estimates and, where applicable, explain why they differ.

Once estimates have been made of the cost per firm/employee of complying with the proposal, the next step is to aggregate these into cost estimates to industry as a whole. Official statistics and enquiries of trade associations or suppliers of the substance are usually required to supplement the data collected for the Criteria Document. Existing exposure information and the enquiry of industry may mean that we can build up an approximate profile of what industry might need to do to comply with the proposal. For example, we might be able to divide the overall number of firms into those who are currently able to comply with the MEL proposal, those who need to do a little more and those who need to do significantly more. Multiplying these by the costs per firm/employee established through the enquiry should mean that we can produce aggregate cost estimates.

It should be emphasised that in most cases these aggregate cost estimates cannot be precise. There will usually be uncertainties on the number of firms/employees affected, how they will be affected and what the cost of firm-specific actions will be. Any cost estimates should therefore usually be taken only as indicators of the overall scale of costs. In some cases HSE will be fairly confident in the estimates, for example where we are able to contact a high proportion of the firms affected (e.g. the CBA for aniline). In others, there may be a particularly high degree of uncertainty. In these cases, costs may be presented in a wide range or, in extreme cases, only a qualitative assessment made (e.g. the CBA for softwood dust). In any event, every CBA will include a section on the uncertainties involved in the assessment. This will identify any key assumptions, discuss the significance of any unquantifiable costs or

benefits, and may present alternative cost and benefit scenarios based upon different assumptions ("sensitivity analysis").

Benefits

Some of the actions taken by firms to comply with a MEL proposal might yield operational benefits, such as increased productivity. These need to be included as benefits (or deducted from costs) to identify the net impact of the proposal on industry. These benefits can sometimes be a significant factor. An extreme case was the MEL for triglycidyl isocyanurate (TGIC), where it was found that reductions in product wastage could, under plausible assumptions, fully offset the cost of the control measures.

However, the principal reason for introducing a MEL is usually to increase protection for workers exposed. The main expected benefit is therefore a reduction in risk of harm to workers. The health effects and studies into the risk to workers at different exposure levels will have been addressed in the Criteria Document. Where risks to workers can be identified at current exposure levels and the reduced exposure levels resulting from the introduction of the MEL, benefits (i.e. number of illnesses prevented) can be quantified using data on the size of the exposed population.

In many cases, however, it is not possible to reliably quantify the number of ill health cases which will be prevented by the MEL. There may be insurmountable obstacles, for example in extrapolating risk estimates from animal data to humans. In other cases it may be possible to provide an illustration of possible benefits. This might make use of, for example, statistics on numbers of people reported as becoming ill as a result of exposure to the substance. These statistics might come from employer's requirements to report certain injuries and ill-health (RIDDOR), through the individual's doctor (SWORD or EPIDERM) or through claims for industrial injury disablement benefit. It needs to be borne in mind, however, that such data will underestimate the true number of people affected, and possibly by a substantial amount. In the CBA it may be reasonable to assume that compliance with the MEL would result in a certain percentage fall in the number of reported ill health cases.

Putting a monetary value on ill-health prevented is a difficult and sometimes controversial issue. HSE takes as its starting point the Department of the Environment, Transport and the Regions (DETR) value of a statistical life (VOSL). This currently stands at about £850,000 and is the most widely used figure across government. It is based upon individuals' willingness to pay (WTP) to reduce risks of road accidents. For many types of work accidents it could be argued that the type of harm is not greatly dissimilar to road accidents and therefore the DETR's VOSL is often used. However, an adjusted approach is more often used for work-related ill health. For example, for substances where exposure can result in cancer, the DETR's VOSL is doubled to allow for individuals' particular dread of this disease.

For some types of non-fatal work-related ill-health a more direct approach is taken. For example, many of the substances for which a MEL is considered can cause asthma. Based upon research, HSE has developed an indicative monetary value for the benefit to society, over a ten year period, of preventing one case of occupational asthma. This currently stands at about £35,000, consisting mostly of loss of income but also includes allowances for medical treatment and pain and suffering.

So, where we are able to quantify the number of ill-health cases expected to be prevented by the MEL proposal, we can, in most cases, attach an overall monetary value to benefits. However, as with costs, the CBA will usually state that these estimates are not precise and, given the particular uncertainties involved, should only be taken as broadly indicative.

Balance of Costs and Benefits

Where we are unable to quantify the possible reduction in risk or ill health cases, we cannot make a direct measure of costs against benefits. Nevertheless, it may still be possible to make some

comparison. For example, by using a VOSL or a value for non-fatal harm, we will be able to assess how many cases of ill-health would need to be prevented to balance costs. This number might then be compared to estimates of the number of people exposed and/or data on number reported as becoming ill, to inform how likely this reduction might be. This comparison does not, however, mean that benefits are necessarily required to match costs. When individual risks are judged to be high, control measures may be required, provided that the costs are not grossly disproportionate to the expected benefits.

Evaluation

All proposals for new health and safety regulation have to include plans for their post-implementation evaluation. Evaluation helps to assess whether the objectives of the regulation, policy or activity have been successful, and can act as a check on the accuracy of the CBA.

HSE has carried out major evaluations of a number of regulations, including the Display Screen Equipment, Noise at Work and COSHH. These were all undertaken a few years after the regulations were introduced, so that the regulations had time to "bed down". To date there has been a major evaluation of one MEL, for silica. The silica MEL was introduced in 1992. The evaluation encountered problems in as far as there was little information pre-1992 to compare with data collected post-MEL. It was also difficult to isolate the impact of the MEL from the more general introduction of COSHH around this time. Also, at the time, CBAs were not undertaken on individual MEL proposals and we cannot therefore check costs and benefits against those estimated before the MEL was introduced. Nevertheless, the evaluation provided useful information on the effectiveness of the MEL and COSHH in reducing exposures and the costs incurred by industry in doing so. The evaluation also provided estimates of what it would cost to reduce exposures further, informing possible future policy proposals. Evaluation of MELs is likely to become increasingly important in the future.

Case Studies

Case Study 1 - Glutaraldehyde CBA

Background

Glutaraldehyde is used primarily in the UK as a biocide or chemical disinfectant.

Occupational exposure to glutaraldehyde was subject to an occupational exposure standard (OES) of 0.2 ppm (15 minutes). HSE's preferred option was for a MEL at 0.05 ppm (15 minute). However, the CBA also considered (more briefly) MELs at 0.02 ppm and 0.1 ppm.

There is no UK manufacture of Glutaraldehyde. However, consultation with the main trade association established that there were an estimated 200 suppliers of formulated Glueraldehyde, where about 600-800 employees were exposed. Nearly all exposures were below the proposed MEL value. The only costs to the suppliers were additional monitoring and RPE.

Of the users of Glutaraldehyde, the main impact was expected to be in the health sector. There were 759 endoscopy suites in 638 hospitals. Exposures reached levels higher than 0.2 ppm where endoscopes were cleaned manually and no control measures were in place.

Costs

An estimate of the cost impact of the proposed MEL on the health sector was obtained through existing surveys and information provided by suppliers of equipment. A survey of 47 hospitals suggested that perhaps 16% (121) of hospitals currently had no controls. Data provided by manufacturers suggested that 47% (357) had autowashers. This left some 37% (281) with some form of control on exposure (ventilated work-benches, semi-enclosed washers). In a survey by NHS Estates, only 1 out of 16 endoscopy suites (6.5%) with controls had exposures above the proposed MEL. From this, we cautiously assumed that 6.5% to 12.5% of the 281 suites with some form of control had to upgrade their controls. For these, and the 121 suites without any form of control, we assumed that they either installed autowashers at a cost of £25,000 or a ventilated workbench at £4,500 (cost figures from the manufacturers).

We therefore arrived at an aggregate one-off cost of £0.625m to £3.9m. The CBA stated that costs were more likely to be at the upper end of the range since hospitals were more likely to purchase autowashers. On-going costs were estimated to be about £0.55m to £0.75m, covering the running costs of autowashers or ventilated work-benches, monitoring costs and maintenance.

Costs in most of the other user sectors were expected to be small since exposures were typically below the proposed MEL.

Over a ten-year period costs were estimated at £8.9m to £15.7m, with about two thirds being incurred by the health sector. It was noted that since most of this expenditure was accounted for by hospitals with no autowashers or current controls, much of this could be attributed to improved compliance with the existing OES, rather than the additional requirements of the proposed MEL.

Benefits

Installing autowashers was likely to result in considerable time savings in the washing of endoscopes. Using conservative assumptions, it was estimated that this could result in a cost saving to the health sector of about £0.5m to £0.75m over ten years.

The main health effect associated with Glutaraldehyde is asthma. Unfortunately, a dose-effect relationship for Glutaraldehyde could not be identified. However, data under RIDDOR, the Department of Social Security (DSS) IIDB scheme and SWORD suggested that the total number of cases of occupational asthma due to Glutaraldehyde could be of the order of 25-50 per year. There were also about 20 cases of skin and eye irritation and sensitisation reported each year. Clearly, there were significant potential health benefits in setting a MEL.

Balance of Costs and Benefits

The CBA calculated that if all of the 25-50 asthma cases per year were prevented by the proposed MEL, then (dividing this into the overall estimated costs) the cost per case of asthma avoided would be about £18,000 to £60,000. HSE's estimated cost of a case of occupational asthma fell within this range. However, since it was unlikely that all cases would be prevented it was concluded that costs were more likely to exceed benefits than vice versa. A comparison of the number of cases being reported with the estimated number of people exposed suggested, however, that the risk to exposed individuals was comparatively high, supporting a judgement that costs were not disproportionate to benefits.

Other Options

An analysis of the cost of the alternatives to 0.05 ppm suggested that the costs of a MEL at 0.1 ppm would only be slightly lower, but that a MEL at 0.02 ppm would be substantially more expensive. It was not possible to evaluate the comparative benefits of these options, but the analysis of costs provided some additional support that the HSE had pitched the proposed MEL at broadly the right level.

HSE are preparing for full public consultation on the proposed MEL for Glutaraldehyde. The CBA summarised above is thus subject to change.

Case Study 2 - Ethylene Diamine

Ethylene Diamine (EDA or 1,2-diaminoethane) can cause occupational asthma, and has also been shown to cause irritant and/or allergic dermatitis. Its major use in the UK is by the chemical synthesis industry as an intermediate in the manufacture of many products including detergents, water and waste separation and as a chelating agent. To a smaller extent it is used in formulations, in the printed circuit board and metal finishing industries and as a curing agent in epoxy coatings/resins.

EDA is not manufactured in the UK. In 1993 approx. 11,000 tonnes was imported from Europe. There are less than ten major users in the UK and only one or two workers are exposed per shift. Less than 100 are exposed in chemical synthesis, and less than 1000 intermittently in manufacture and end-use of products containing EDA. The usage of EDA in epoxy resins has now reduced to four companies involved in hardener manufacture, and downstream use of formulations (where more people are potentially exposed) is restricted to formulations containing 2% or less EDA.

When HSE reviewed the industrial usage of EDA in the early 1990s to help prepare the risk assessment document, the number of workplace usages and numbers of people potentially exposed suggested that a maximum exposure limit would be appropriate. HSE reviewed the industry again in 1997 to update the information and prepare the arguments for ACTS to consider in setting a MEL. The new data showed considerable changes in usage and in particular that:

- fewer people are exposed to EDA than previously thought
- exposure levels are much lower than predicted
- all exposure measurements were below the level of detection.

HSE considered these findings and decided that preparing a CBA would not add to the discussion and that a policy decision could be made without one. HSE believes that industry had responded to concerns about the health effects of EDA, or industry had anticipated that an exposure limit was to be set and had taken appropriate measures, either by substituting EDA for a less toxic substance, or by control measures that reduced potential exposures.

HSE recommended to ACTS that setting a MEL for EDA would not be appropriate in these circumstances, as:

- a MEL would give no added value of control
- MELs should only apply to substances with potentially significant hazards and risks
- the identified health hazards of EDA are currently well-controlled
- as exposure is judged by HSE to be negligible, a limit would have little impact
- COSHH provides an adequate framework for control.

Case Study 3 - Aniline

Exposure to aniline has been found to cause carcinogenicity and mutagenicity in animals. It is considered that the same health effects can occur in humans, although there is no relevant human data. It is classified under the CHIP Regulations as a cat. 3 carcinogen.

Aniline is used in the manufacture of fine chemicals, rubber chemicals and dyes. The only UK manufacturer is currently expanding capacity from 200,000 to 300,000 tonnes pa, of which a substantial proportion is exported. Around 500 people are exposed to aniline at work in the UK during manufacture, distribution and use.

All known exposures to aniline are currently controlled to below 1 ppm. ACTS considered the arguments for setting the MEL at a level of 0.5 ppm or at 1 ppm. Most companies are able to comply with a MEL set at 0.5 ppm (8 hour TWA). However, because of technological difficulties conducting remote sampling - requiring the use of respiratory protective equipment (RPE) - some companies would be unable to meet the short-term guidance value of three times the MEL limit. Costs would be incurred in providing the RPE and its frequent use increases the risk of skin contact with repeated use of contaminated gloves. Skin exposure in the workplace has significant potential to lead to a higher uptake of aniline than via inhalation alone.

Costs

The costs of setting a MEL at 0.5 ppm were estimated at £300,000 to £600,000 and for a MEL at 1.0 ppm at £77,000 over 10 years. Most of the costs incurred in meeting a level of 1.00 ppm would be for additional monitoring.

Benefits

The absence of suitable data meant it was not possible to quantify the health benefits for reducing the risks of cancer. All that could be said was that reducing exposure would reduce the risk.

Conclusion

The CBA provided a useful comparison of the costs of the two options. It was not possible to quantify the additional benefits of the lower MEL, so a comparison of costs and benefits was not possible. Moreover, the key factor in the decision was the technical difficulty in keeping short-term exposures below the lower MEL. A comparison of costs and benefits was not therefore a factor in the decision, although the CBA helped to identify these technical difficulties.

A further important factor in the decision was that the definition of a MEL requires exposure to be controlled to as low as is reasonably practicable below it - therefore those employers already controlling to below 0.5 ppm would be expected to continue to do so and reduce even further if practicable.

The Role of Socio-Economics in the Development of Management Options for Perchloroethylene

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Background

Tetrachloroethylene, also known as perchloroethylene and commonly referred to as PERC, was assessed as toxic pursuant to the *Canadian Environmental Protection Act* (CEPA). According to the Act, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term effect on the environment or human health (see Government of Canada, 1996).

The environmental toxicity of PERC was mainly based on the finding that ambient air concentrations could under certain circumstances harm certain plants. Limited data also indicated that PERC concentrations in some surface waters replenished by contaminated ground water exceeded the toxic level for the most sensitive aquatic species. Exposure levels of the general population of Canada were found to be below the tolerable daily intake. However, given the small “margin of safety”, any actions that would further reduce human exposure to PERC were deemed desirable from a health protection viewpoint. Recent surveys of ground water contamination supported the need for controls on the use and disposal of PERC (see Government of Canada, 1996).

To ensure that the most effective and efficient options are addressed, within the context of sustainable development and pollution prevention, the Strategic Options Process (SOP) was developed as the consultative mechanism in the decision making process. The principles of this approach are:

- public participation
- openness and transparency to all partners and stakeholders
- exploring instruments beyond traditional command and control regulations (e.g., use of economic instruments)
- cost-effectiveness - when assessing the management tools to be recommended to Ministers
- flexibility, such that differing environmental/socio-economic conditions and regional differences are taken into account
- cross-sectoral equity - responsibility for toxics control will be allocated across all sectors contributing to the problem.
- harmonizing the environmental management of CEPA toxic substances among federal and provincial governments.

The stakeholder consultations were led by Environment Canada with Health Canada as a key participant. Other federal departments and provincial governments are all key players with shared responsibility in managing toxic substances. Industry, aboriginal groups and non-governmental organizations (e.g., environmental, labour) are invited to participate.

All participants in the process determine their own level of participation. From Environment Canada's perspective, it is important that participants with scientific, technical and economics expertise support the initiative from the beginning of the process through to its conclusion. The SOP provides the basis for recommendations to the accountable ministers. Through discussion, the federal and provincial governments determine which level of government should implement the recommendations of the Working Group.

The focus of this paper is on the role of the economist within the dry cleaning sector SOP who analysed the cost-effectiveness of the various management options that were tabled for discussion.

Role of the Economist

In the department's development of a strategy, the Chair of the multistakeholder Working Group engaged technical staff as well as an economist. The economist's role was to provide overall economic support and analysis to the Working Group. Prior to initiating the work of the Working Group, it was understood that the economist would be involved in three major components:

- development of a socio-economic profile, which was to provide background data on the nature of the dry cleaning sector
- qualitative analysis of a wide range of management options for consideration by the Working Group
- full quantitative analysis of a narrower range of management options selected by the Working Group.

Each of these elements is discussed in more detail below.

Socio-economic Profile

Background socio-economic information on the sector was generated from two surveys: one of dry cleaners and the other of household expenditures on dry cleaning. In both cases, overall data quality was good, and therefore could be used for later components of the analysis. The socio-economic profile provided information on the number of facilities by type of solvent used, type and age distribution of machines, annual revenues of cleaners, number of employees, and annual operating costs.

The survey of household expenditures showed how much Canadians spend on dry cleaning services. From this, an estimate of revenues generated by the industry and average profits could be calculated. All these data would eventually be used in the quantitative analysis of the management options selected by the stakeholders.

Qualitative Analysis

As noted above, the first step in the assessment of options was to undertake a qualitative review of a wide range of potential tools. These management tools that were considered included:

- regulations
 - mandatory technology performance standards
 - Canadian Council of Ministers of the Environment (CCME) guidelines
 - transfer machine ban
- mandatory training

- economic instruments
 - cap and trading permits at different levels (importers, distributors, dry cleaners)
 - charges/levies applied at different levels (importers, distributors, dry cleaners)
 - financial incentives
 - operator training
 - capital equipment replacement
 - waste disposal
- voluntary actions
 - non-structured agreements
 - structured agreements
 - compliance with guidelines developed by CCME

The criteria against which these tools were measured, together with the challenge questions, were as follows:

- environmental effectiveness
 - To what extent can the environmental/health targets be achieved with the use of this management tool?
- cost-effectiveness
 - Will this tool minimize the financial burden to industry and to government in dealing with the target?
 - What impact on competitiveness will result from the use of this tool to achieve the environmental objective?
- monitoring and enforcement
 - How easily can one enforce and monitor compliance with this tool?
- legal implications from a federal perspective
 - Is the enabling legislation for this tool currently available?
- support of the Working Group
 - Based on discussions within the Working Group, how acceptable will this tool be to the various stakeholders?

A number of other criteria have been used as well: incentives to stimulate creativity and innovation; potential for economic growth; speed with which the target could be achieved; data requirements to use the tool in terms of quality and availability; and public acceptability.

The results of the qualitative analysis above produced three groupings of options reflecting the initial interests of the Working Group:

- technology regulations and mandatory training
- staged declining quotas on PERC imports
- levy on PERC sold for dry cleaning use.

Up to this point in the process, the role of the economist in the Working Group had been to produce background information in conjunction with other stakeholders, and to lay out the qualitative analysis so that a fruitful discussion of a wide range of management options can take place. What is important to note is that the economist was part of this exercise from the very beginning of the consultations, and by now had developed a good understanding of the technical issues within the dry cleaning sector, as well as gaining an appreciation of the different interests among stakeholders. The economist was able to make a substantial contribution to discussions on the options. In effect, the economist's role, in addition to that of providing economic advice and support, expanded so as to include that of providing substantive input to the decision making process.

The next step in the process was to take the three main options discussed above, and to refine them for further analysis. Based on the quantitative analysis and discussion of policy preferences amongst the Working Group, a fourth management option was added. This option was based on mandating technology and operator training, and introducing a levy on PERC to offset the costs of operator training, waste disposal and facility monitoring/inspections. The resulting groupings from the qualitative analysis were extensively discussed by the Working Group, with advantages and disadvantages of each being considered. We now move to the stage where full quantitative analyses of these four options were undertaken.

Full Quantitative Analysis⁶

What is important to recognize at this point in the analysis is that the Working Group now proceeded to consider the results of the economic analysis in terms of the most appropriate recommendations to be made as part of the Strategic Options report. What was required was to determine the costs and benefits associated with each option, in order to arrive at a net benefit value. A cost-benefit analysis was used to evaluate the four options.

Environmental benefits are linked to the avoidance of environmental damages to: 1) terrestrial plants and 2) ground water generated by the discharges of PERC to the environment. Benefits were determined through the use of a survey which asked Canadian households how much money they were willing to pay on their annual dry cleaning bills in order to eliminate the environmental damages associated with PERC. A second measure of benefits used was that of avoided costs, which was represented by the financial costs associated with replacing PERC contaminated ground water used for municipal water supply (see Government of Canada, 1996).

Costs to dry cleaners for each of the options were based on the assumptions of constant prices and demand for dry cleaning services. In order to assess distributional effects within the industry, facility types were grouped into several annual revenue categories. The model used simulated choices for cleaners to choose amongst a number of different possible technology combinations. It was assumed that dry cleaners would choose the least cost technology combination for each of the options considered.

Costs to government were based on actual practice either in Canada or in other countries for the mandatory technology and import quota options, while the levy options assumed administrative costs would amount to 10% of the total levy revenues. Administrative costs were assumed to be recoverable within the levy, making the levy options revenue-neutral to government.

The major data sources for the analysis included the following: an engineering feasibility study, a survey of the Canadian population regarding dry cleaning use and pricing, and a municipal survey regarding ground water remediation costs. Other information was provided by distributors of PERC and by waste disposal firms.

The results from the survey indicated that, on average, Canadian households would be willing to pay up to almost 8% more on their average annual household expenditure for garment cleaning. An interesting point can be made when one compares this to the fact that the expected price increase charged by dry cleaners would be 3%. This price increase also would not substantially affect the level of demand for dry cleaning services. This conclusion results from the cost structure of dry cleaning, where costs associated with PERC use (capital, solvent, electricity, waste, etc.) represent a small proportion (5%) of total operating costs. Major costs for dry cleaning include labour (approximately 53%) and the costs associated with plant siting (approximately 42%).

What were the results of the economic analysis? Based on a ten-year time frame, the analysis showed that benefits exceeded costs for all four options, with the levy/subsidy option resulting in the highest net benefits. The levy/subsidy option had the lowest cost to dry cleaners of all options modelled. However, this option could not achieve the environmental target of 70% reduction in PERC releases. It could not achieve the target because this option would not result in substantial replacement of old machinery, though it would generate improvements in operating practices through higher prices paid for PERC.

The option with the second highest net benefit was the option that combined mandatory technology replacement with a levy/subsidy. This option generated both the highest cost to dry cleaners and the highest benefits of all options analysed. It generates the highest costs, as dry cleaners must pay for both new machinery and increased prices for PERC. This option, along with the import quota option, were the two options which achieved PERC use reductions of over 70%. A ranking of the various options based on cost effectiveness (i.e., cost per tonne PERC use reductions) generates the same result.

What do these results mean for the industry? Cost increases to industry under any of the scenarios would be unlikely to significantly increase the price for garment cleaning, and thus demand would stay relatively stable. This is because in a highly competitive industry, certain industry segments (e.g., large firms with modern equipment) would not be impacted by the regulations, while others (e.g., small firms with older equipment) would see increases in costs. Due to the competitiveness of the market, it is likely that the firms impacted by the regulations could not pass on their cost increases to consumers through higher prices, and thus would have to reduce their profit margins.

The impact of the options including mandatory technology is primarily in terms of changes to the structure of the industry. Older equipment is disproportionately used by the small revenue dry cleaners, who also have the most difficulty in raising capital to purchase new equipment. The pressure on the profits of low revenue dry cleaners with older equipment may cause substantial market exit, or transformation into store-front outlets. Low revenue cleaners with older equipment represent 30% of the industry by number and clean approximately 11% of all garments.

Considerations

The results of the economic analysis were presented to the Working Group for their consideration. Although views varied widely, the option receiving the greatest support was the one that combined mandatory technology/training and a levy on PERC (second highest net benefits). The economic analysis showed that the projected reduction in PERC use could only be attained by either the import quota option or the combined mandatory technology/training and levy/subsidy option. Legal advice provided indicated that domestic quotas might be inconsistent with international trade agreements, thus leaving only one option that would generally be accepted. The economic analysis supports this option, but,

as noted above, would cause major dislocation within the industry, with small dry cleaning shops with lower profit margins and older equipment being the most affected.

It is interesting to note that the dry cleaners fully supported government regulatory measures and initially opposed a levy on PERC and strongly opposed quotas. The view on the levy changed and was adopted by industry when it was modified to provide revenue to offset plant inspections and operator training.

The selection of management options from the qualitative analysis is prefaced on the condition that the selected option(s) would result in a reduction of PERC consumption within a set target range (i.e., 60-90% decrease), thus eliminating any environmental impacts. The implementation of the SOP recommendations, including the combined mandatory technology and levy/subsidy option supported by the Working Group, is expected to reduce PERC consumption by 70%. Successful implementation of the recommendations will depend on the willingness of all partners to work together to achieve a complete management package for PERC in the dry cleaning sector.

Lessons Learned

In this specific case, economics played a key role in the final determination of viable options that were acceptable to the majority of stakeholders on the Working Group. Economics support was part and parcel of this initiative from the outset, thus allowing for full participation by an economist in the discussions and negotiations. It is generally accepted that an economist is able to provide an analytical perspective that is one of the prime considerations in developing the final recommendations forwarded for the Ministers' decision.

In fact, one of the important considerations in the federal government Regulatory Policy (as prepared by the Treasury Board Secretariat) is the need to show that the benefits of regulation or any other control option exceed the costs. Although quantifying environmental benefits is a difficult task which is often largely limited by the quality of input data, in this exercise we were able to derive a credible set of estimates.

In Canada, the economic analysis undertaken will form the basis for the Regulatory Impact Analysis Statement (RIAS), which must be prepared for all regulatory initiatives. The RIAS consists of the following: description of what is being proposed; alternatives considered and why regulation is the best approach; costs and benefits of the proposal (could be cost-benefit analysis, cost effectiveness analysis, etc.); consultations undertaken and whether agreement was reached with those consulted; and compliance mechanisms to ensure compliance with the proposed regulations.

With a draft regulation in development, it is obviously impossible to either assess or predict the accuracy of the estimates made in the cost-benefit analysis, or predict whether the targets for PERC reduction will be achieved. An important shortcoming of regulatory programs in Canada, for reasons of cost, has been a lack of environmental monitoring that would measure improvements in the environment associated with the control actions being taken.

One of the elements yet to be resolved is the recommendation on the levy. The enabling legislation for such a levy, which currently resides with the Department of Finance, is not well suited for environmental purposes. It is relatively difficult, for example, to adjust the levy once in place. In addition, the dedication of funds raised through this authority will be problematic, especially as the recommendation is to use the fund for operator training which falls in an area of provincial jurisdiction. The feasibility of using this type of economic instrument is still being assessed.

Conclusion

The Strategic Options Process for PERC has shown the important role that economic analysis has in evaluating environmental management options. It is unlikely that a meaningful discussion of the various options at the Working Group would have taken place without the economic analysis undertaken. In addition, the timeliness of analysis has allowed for a quicker preparation of the RIAs, as the essence of the assessment of the costs and benefits had already been performed.

In the development of management options for pollution control programs, it is critical to include economic considerations brought forward at the outset. The nature of the analysis will be a function of the complexity of the issue under consideration. In the case discussed, a full cost-benefit analysis was performed, but may not be necessary all the time. But in all cases, economic analysis is crucial.

Notes

1. Environment Canada economist for this initiative (currently employed with Transport Canada).
2. Health Canada risk manager.
3. Environment Canada technical support to the Working Group.
4. Currently employed by Environment Canada.
5. Environment Canada - Chair of the Working Group.
6. See Government of Canada, 1996 and Environment Canada (Economic Impact Analysis), 1996 for detailed analysis and results.

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A Case Study In Cost-Benefit Analysis: An Air Quality Standard for Lead

David Wilson, Lead Development Association International

Background

In September 1996 the Council of the European Union adopted Council Directive 96/62/EC on ambient air quality assessment and management. The aim of the Directive is to establish objectives for ambient air quality in the Community in order to avoid harmful effects on human health and the environment. A key element of this process is the establishment of ambient air quality limit values, together with guidance on how and where measurements should be made. Economic and technical feasibility are identified as factors which may be taken into account when setting limit values.

The first pollutants for which limit values are to be set were identified as sulphur dioxide (SO₂), nitrogen dioxide (NO₂), particulate matter and lead, on the grounds that limit values had already been set some years ago and were in need of revision. Working Groups for each pollutant were convened in early 1996 (before the Directive had been adopted) and recommendations for limit values proposed by the Commission in October 1997, after the Working Groups had delivered their conclusions and cost-benefit analyses had been conducted by independent consultants.

Health Effects of Lead

Lead is a metal which has been used by man for thousands of years. It is produced and used in large quantities in all parts of the world and is extensively recycled. Because of this anthropogenic activity, and because lead is mobilised by natural events such as volcanoes, everybody is exposed to the metal to varying degrees.

Lead is also known to have harmful effects on human health. Exposure is generally measured in terms of the concentration of lead in blood (in µg/dl) and there is much debate about the precise levels at which these harmful effects occur. However as scientific knowledge and understanding of the effects has improved over the years, the levels of acceptability have been slowly reduced.

The most serious effect - clinical lead poisoning - results from extremely high levels of exposure and is very rarely seen these days. In the area of occupational exposure, the upper permissible blood lead limit in most countries is of the order of 50-70 µg/dl, with a general downward trend towards the lower end of this range and a few countries moving towards 40 µg/dl. The health effects which these limits are designed to protect against include anaemia, reduced kidney function and damage to the central and peripheral nervous systems.

Occupational exposure limits are designed to protect healthy adults who are subject to ongoing medical surveillance, and so lower limits are considered more appropriate for the general population. There is a general acceptance that young children represent the most vulnerable segment of the population and the critical health end-point for them is normally regarded as IQ (intelligence quotient), the nature of the effect being that an increase in blood lead levels may result in a slight decrease in IQ.

The assessment of impacts on IQ is notoriously difficult. Many confounding factors need to be taken into account (e.g. parental intelligence, socio-economic class, quality of parent-child interaction, etc.). Moreover, changes are small in magnitude and can only be detected for population groups, not for individuals. Nevertheless a consensus of sorts has emerged in several countries that a blood lead level of 10 µg/dl should represent a “level of concern” for young children and that public health programmes should be designed to avoid children exceeding this level.

Derivation of an Air Quality Guideline for Lead

In order to provide a starting point for the deliberations of its Working Group on an air quality standard for lead, the European Commission invited the World Health Organization to update its 1987 Air Quality Guideline for lead. A new guideline was duly developed for lead, and also for the three other pollutants under review - SO₂, NO₂ and particulate matter.

In the case of lead the WHO adopted the 10 µg/dl blood lead level as the basis of its calculations, the objective being to derive a recommended air quality value which would ensure that 98% of exposed children enjoyed blood leads below 10 µg/dl. In order to perform such a calculation it was necessary to make a number of assumptions about such matters as the contribution of air lead to blood lead in young children and the expected blood lead levels of non-exposed children. By its own admission WHO made a number of conservative assumptions in its derivation and applied generous safety factors. It also, in the view of industry at least, employed one questionable mathematical calculation. The result was an Air Quality Guideline of 0.5 µg/m³ applied as an annual average.

The WHO guideline was presented to the EC Working Group on lead - which comprised representatives of three Member States, industry, NGOs, the European Environment Agency and the EU Joint Research Centre - as the starting point for discussions. It soon became apparent that, with the imminent elimination of lead from gasoline, an air quality standard of 0.5 µg/m³ should be readily achievable almost everywhere throughout the European Union. The only places where difficulties were likely to be experienced were in the immediate vicinity of certain lead producing or processing operations - notably primary and secondary metals plants. Some participants felt that 0.5 µg/m³ was unnecessarily severe, others that it was insufficiently strict. The majority concluded that it was an appropriate level for a new air quality standard, and 0.5 µg/m³ as an annual average therefore became the official recommendation of the Working Group.

Cost-Benefit Analysis

In accordance with the guidance given in the Directive on ambient air quality assessment and management, the Commission of the European Communities retained consultants to conduct an economic evaluation of a set of air quality targets for the year 2010 for SO₂, NO₂, particulate matter and lead, based on the recommendations of its four Working Groups. For SO₂, NO₂ and particulate matter the values to be assessed were multiple targets based on hourly and annual averages, in order to take account of both short-term (acute) and long-term (chronic) exposure. For lead, which has no short-term acute effects, only the 0.5 µg/m³ annual average was subjected to the economic evaluation. The targets investigated for all four pollutants are given in Table 1.

The approach adopted by the consultants in conducting their economic evaluation comprised four main steps. The first step involved the construction of EU-wide reference scenarios for the emissions of the four pollutants. Second came an assessment of the future air quality which could be expected to result, comparison of this with the proposed EU air quality targets and hence an assessment of areas which would be unlikely to comply. The third step comprised an estimation of the costs which would have to be incurred in achieving compliance in the non-attainment areas, and the fourth step was an estimation of the

benefits associated with achieving compliance. Having completed these four steps, a comparison could be made of the costs and benefits of the proposed targets for each pollutant.

Assessment of Costs of Emissions Control

For SO₂, NO₂ and particulate matter significant emissions arise from a variety of sources such as motor vehicles, power generation, other industrial processes and domestic heating. Reductions of varying magnitudes are anticipated as a result of current and planned legislation, with the result that by the year 2010 it was concluded that risks of being exposed to concentrations over the proposed limit values would exist only in major cities. The numbers of people at risk were estimated at 18 million for SO₂ and particulate matter and 30 million for NO₂. Costs of compliance were estimated at 35m ECU (SO₂), 72.5m ECU (NO₂) and 200-500m ECU (particulate matter).

Lead turned out to be a completely different proposition from the other pollutants. Current emissions are dominated (in some countries) by the use of gasoline additives, but by 2000 the application will have been phased out in all EU Member States with the result that the only areas of anticipated non-compliance in 2010 will be in the immediate vicinity (i.e. within about 1 km) of certain non-ferrous metals smelters. Because air quality around smelters is very dependent on the technology and layout of each site, the cost estimates for compliance with a 0.5 µg/m³ standard had to be analysed on a case-by-case basis. Data were obtained for about half (in capacity terms) of European plants and half of these were estimated to need additional investments. The number of people living in zones where the standard was likely to be exceeded was estimated at between 10,000 and 30,000.

The necessary investment costs for primary lead smelters were estimated variously at between 129 and 432 ECU/tonne of installed capacity, which conformed with actual costs of 216 ECU/tonne for a plant which had already invested in new plant which enabled the proposed 0.5 µg/m³ standard to be met. On a plant by plant basis, the costs ranged from 13-19m ECU per plant. The figures were also of similar magnitude to US industry estimates of emission reduction costs. By extrapolating the figures to total European primary lead capacity, the consultants derived total estimated costs of between 65 and 200m ECU, or annual costs of between 12 and 40 million ECU.

For secondary smelters the corresponding investment data were between 85 and 430 ECU/tonne of installed capacity or, on a plant by plant basis, between 2.3 and 13 million ECU, with the highest figure relating to the smallest plant. These figures were not scaled up to give a total cost for the European secondary lead industry and no costs for the secondary industry were included in the final cost-benefit analysis. Moreover the consultants acknowledged that there might also be costs for some lead processing plants, e.g. lead-acid battery manufacturers, but no attempt was made to assess them.

The estimated costs of meeting the required emissions reductions by 2010 for each of the four pollutants are summarised in Table 2.

Estimation of Benefits

In order to estimate the benefits of the proposed reductions in air quality limit values, judgements had to be made on the health end-points which would be affected and monetary values had to be assigned to those health end-points. Combining these figures with the number of people who would experience improved air quality and the percentage improvements which could be expected in each health end-point gave a monetary value to the benefits.

The main health effects attributed to the pollutants in the analysis were divided into short-term (acute) and long-term (chronic) effects. Amongst the short-term effects were premature mortality due to respiratory or cardiovascular problems and a wide range of non-lethal but debilitating respiratory

problems, all resulting from a short period of peak concentrations. Long-term effects related to annual average concentrations again included mortality and respiratory illnesses, but also included the possibility of IQ decrements in children in the specific case of lead. Percentage changes in the risks for each end-point which could be expected to result from the proposed reductions in air quality limit values were taken from the published literature. Baseline risk factors (quantified as the rate per 1000 persons) were also taken from the literature.

For the four pollutants under consideration there were a number of common health end-points of importance but also some significant differences. SO₂, NO₂ and particulate matter were all held to be responsible for a number of acute effects. NO₂ and particulate matter were also considered to cause a range of chronic health effects. Lead was only responsible for chronic effects. A summary of the numbers of people for whom an impact reduction could be expected as a result of the air quality proposals is given in Table 3.

The valuation of health effects was inevitably a difficult and potentially controversial issue. For mortality the so-called "value of a statistical life" was used, based on estimates of people's "willingness to pay" to reduce annual risks of mortality. For morbidity, willingness to pay to prevent suffering from illness was again a component in the valuation process, as also were costs of medication and decreased productivity of the patient. The consultants were unable to find published cost data for all the health effects under consideration but monetary values for those effects that could be costed are given in Table 4.

With all necessary data now assembled, it was possible for the consultants to calculate a monetary value for the health benefits which should result from the proposed new limit values. For SO₂, NO₂ and particulate matter the benefits were dominated overwhelmingly by reduced cases of chronic mortality. Chronic mortality also featured for lead (see Table 5) with an expected saving of about one-third of a death per year. The other costed benefit for lead related to reduced decrements in children's IQ. The total economic benefit for health impacts from lead was put at 3.2-5.8 million ECU per year. The figures for all four pollutants are summarised in Table 6.

Comparison of Costs and Benefits

Having completed all steps of their economic evaluation, the consultants were in a position to compare the costs and health benefits of pollution reduction for each of the four pollutants. The results are given in Table 7, which also gives a benefit-cost ratio for each pollutant. For SO₂, NO₂ and particulate matter benefits exceeded costs by a significant margin, giving benefit-cost ratios well above one. The conclusion drawn was that, on socio-economic grounds, a reduction of these pollutants to the limit values proposed is a sound decision. However, for lead costs exceeded benefits, giving a benefit-cost ratio well below one, resulting in the observation that a similar conclusion could not be drawn.

European Commission Proposals for New Air Quality Limit Values

On 8 October 1997, the European Union adopted a draft Council Directive proposing new air quality limit values for SO₂, NO₂, particulate matter and lead. These values were in each case the ones derived from the work of the earlier Working Groups and subsequently submitted to cost-benefit analysis. Whilst numerically the same, however, the target dates for achievement of these values had in several cases been brought forward from 2010.

For SO₂, NO₂ and particulate matter the adoption of these values is not surprising in the light of the cost-benefit analysis which considered them to be sound on socio-economic grounds. For lead, however, the adoption of the 0.5 µg/m³ annual average limit value is more of a surprise since it could not be supported on socio-economic grounds. It is even more surprising that the target date for compliance has been brought forward from 2010 to 2005. Although costs and benefits are referred to by the European

Commission, it must be assumed that the decision has been taken to ignore the findings of the cost-benefit analysis.

For the lead industry the consequences of a $0.5 \mu\text{g}/\text{m}^3$ air quality standard, if adopted, will be severe for a small number of plants which will be obliged to invest heavily in new control and/or process technologies, or cease operating. The costs are all the more severe because they are not recoverable through the conventional mechanism of increasing the price of the product being manufactured, thus passing on the costs to the customer. Lead - like all metals - is sold at prices determined on the London Metal Exchange, an independent trading mechanism which takes pricing control out of the hands of the producers.

The numbers of people who stand to enjoy health benefits from the proposed standard are very small and decreasing all the time. Intake of lead can result from a variety of sources - not only lead in air - and many measures are in hand to reduce exposures. This is evident in the continuing declines in blood lead levels being seen around the world, including in all Member States of the European Union (see Figure 1). As these declines continue, which can be confidently expected, the number of individuals for whom lead in air will raise their blood lead level above the $10 \mu\text{g}/\text{dl}$ level on which the proposed standard is based will also decline. This will alter further the cost-benefit ratio for a $0.5 \mu\text{g}/\text{m}^3$ standard and make it even less justifiable on socio-economic grounds.

Given the very small and declining numbers of individuals concerned, the marginal nature of the expected health benefits, the conservative nature of the calculations on which the recommended standard is based and the fact that a small number of companies will face extremely high and unrecoverable costs (or closure), it does seem remarkable that the cost-benefit analysis has not influenced the Commission's choice of a recommended air quality limit value. A value higher than $0.5 \mu\text{g}/\text{m}^3$ would certainly seem to be justified on the basis of the evidence available.

Conclusions

The development of the first air quality limit values under the EU Council Directive on ambient air quality assessment and management has provided an interesting trial of the process of cost-benefit analysis.

Proposed standards for four pollutants have been subjected to analysis by independent experts, with the conclusion that three of them are justified on socio-economic grounds but the fourth is not. Whilst the wording of the Directive does not demand that costs and benefits be factored into the process but rather indicates that "account shall be taken, by way of example" of economic and technical feasibility, it does seem strange that the findings for lead have not apparently influenced the recommended limit values. This is especially so in view of the small number of locations involved, the small numbers of individuals potentially affected, the declining nature of the problem and the potential damage to the companies concerned.

Cost-benefit analysis is a useful tool which can help to determine the best course of action when decisions need to be taken on a combination of technical and socio-economic grounds. If the tool is to have credibility it needs to be used objectively and dispassionately.

Table 1. Examined air quality limit values ($\mu\text{g}/\text{m}^3$)

Pollutant	
NO ₂	40 $\mu\text{g}/\text{m}^3$ annual average of hourly values 200 $\mu\text{g}/\text{m}^3$ (hourly average) not to be exceeded more than 8 hours/year 30 $\mu\text{g}/\text{m}^3$ (annual mean to protect vegetation)
SO ₂	125 $\mu\text{g}/\text{m}^3$ (daily average) not to be exceeded more than 3 times/year 350 $\mu\text{g}/\text{m}^3$ (hourly average) not to be exceeded more than 24 times/year 20 $\mu\text{g}/\text{m}^3$ annual (and winter) mean for vegetation
PM ₁₀	50 $\mu\text{g}/\text{m}^3$ (daily average) 20 $\mu\text{g}/\text{m}^3$ (annual average)
Lead	0.5 $\mu\text{g}/\text{m}^3$ (annual average)

Table 2. Estimated costs of required emission reduction in 2010 (in ECU of 1996)

	Measures	Total emission reduction (tonne)	Annual costs (million ECU)
SO ₂	Reduction of process emissions Use of low sulphur fuels	78,000	35
NO ₂	Traffic: road pricing and introduction of LPG/CNG buses	7,200	3.5
	Stationary sources: various measures (e.g. low NO _x combustion techniques)	27,000	69
PM ₁₀	Traffic: see above	4,000	80
	Application of fabric filter instead of electrostatic precipitators, but many other measures are applicable	28,000	125-420
Lead	Various measures not separately identified	Not quantifiable	12-40

Table 3. Impact reduction (mid estimates) (number of cases). Rounded figures

	PM ₁₀	SO ₂	NO ₂	Lead
Number of people included in analysis (million)	38	75	80	EU-wide
Number of people at risk (million)	18	18	30	0.01-0.03
Acute (short-term) effects				
Mortality	1000	700	600	
Hospital emergency room admissions	800	300	1300	
Respiratory syndromes children	1000			
Restricted activity days (adults)	15,000			
Chronic (long-term) effects				
Mortality	13,000			0.35
Respiratory morbidity children	9,000		2000	
Respiratory symptom prevalence	25,000			
Decrements in lung function	-150			
IQ-points decrement				700

Table 4. Monetary values of health end-points

	Monetary values in ECU/case		
	Low	Medium	High
<i>Short-term effects</i>			
• Total premature mortality	n.q.	n.q.	n.q.
• Respiratory premature mortality	n.q.	n.q.	n.q.
• Cardiovascular premature mortality	n.q.	n.q.	n.q.
• Hospital emergency room admissions (respiratory disease)	5,188	n.q.	6,600
• Bronchodilator use	n.q.	n.q.	n.q.
• Upper respiratory symptoms adults	n.q.	15.8	n.q.
• Upper respiratory symptoms children	n.q.	15.8	n.q.
• Lower respiratory symptoms adults	n.q.	12.0	n.q.
• Lower respiratory symptoms children	n.q.	12.0	n.q.
• Cough	n.q.	6.3	n.q.
• Symptom exacerbation (prevalence) among asthmatic adults	n.q.	28.1	n.q.
• Symptom exacerbation (prevalence) among asthmatic children	n.q.	28.1	n.q.
• Pulmonary function change (% change in mean level)	n.q.	n.q.	n.q.
• Reduced activity days per adult per year	33.3	n.q.	62.0
<i>Long-term effects</i>			
• Long-term mortality	2,600,000	n.q.	4,200,000
• Long-term respiratory morbidity adults	n.q.	n.q.	n.q.
• Long-term respiratory morbidity children	n.q.	n.q.	n.q.
• Respiratory symptom prevalence adults	n.q.	28.1	n.q.
• Respiratory symptom prevalence children	n.q.	28.1	n.q.
• Decrements in lung function adults	n.q.	n.q.	n.q.
• Decrements in lung function children	n.q.	n.q.	n.q.
• Decrements in IQ in children	1,233	n.q.	5,566

n.q. not quantified

Table 5. Emission reduction of lead. Reduction of health impacts and their economic benefits. 30,000 people, average concentration reduction from 0.75 to 0.5 µg/m³

	Impact reduction in cases/y			Benefit in million ECU/y		
	Low	Medium	High	Low	Medium	High
<i>Long-term effects</i>	n.q.	0.35	0.43	n.q.	1.20	1.80
• Cardiovascular mortality in adults	n.q.	0.001	0.001	n.q.	0.00	0.00
• Cardiovascular mortality in adults due to change in blood pressure		691	720	n.q.	2.35	4.01
• Decrements in IQ in children					3.55	5.81
Sub-total						

n.q. not quantified

Table 6. Impact categories and the results of monetary quantification of benefits (million ECU)

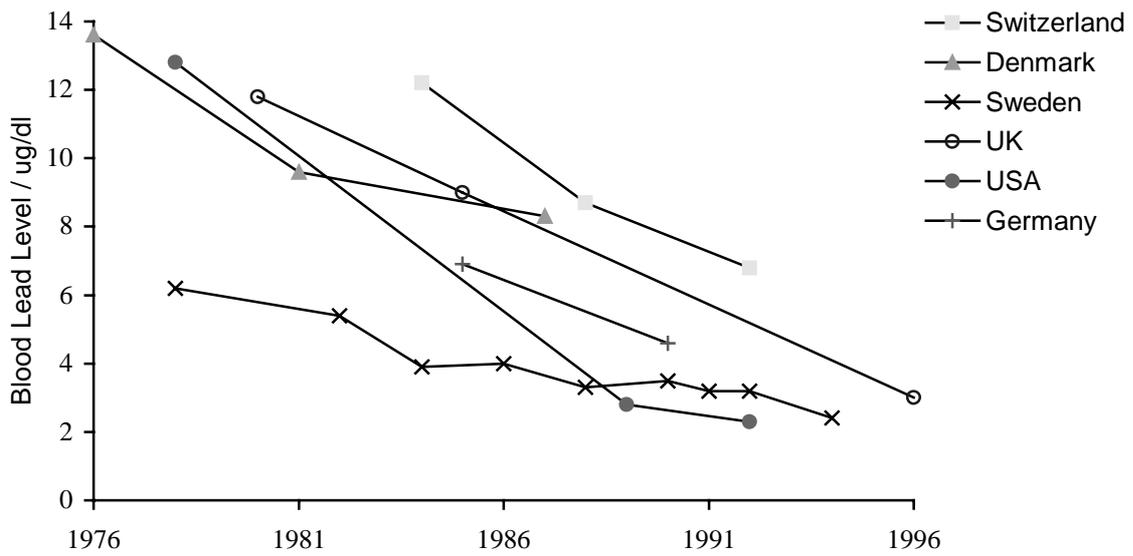
	PM ₁₀	SO ₂	NO _x	Lead
Population in analysis (million)	38	75	80	EU-wide
Population at risk (million)	18	18	30	0.01-0.03
Mortality, acute	n.q.	n.q.	n.q.	-
Mortality, chronic	9,000-85,000	800-4,000	700-1,700	1.2-1.8
Morbidity, acute	2-7	2-4	0-36	n.q.
Morbidity, chronic	0.3	n.q.	n.q.	n.q.
IQ points decrement	-	-	-	2-4
Total (range)	9,000-85,000	800-4,000	700-1,700	3.2-5.8

n.q. not quantified

Table 7. Costs and health benefits of pollution reduction (million ECU)

	Costs	Benefits	Benefit-cost ratio
SO ₂	35	800-4,000	22.8-114
NO _x	72.5	700-1,700	9.6-23.4
PM ₁₀	200-500	9,000-85,000	25.7-240
Lead	12-40	3.2-5.8	0.11-0.37

Figure 1: Decline in blood lead levels



Data taken from the published literature

Chemicals Risk Management under Responsible Care Pesticide Container Management - A Cost-Effective Risk Reduction Approach

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Early in this century, a US telecommunication CEO stated:

“All business in a democracy begins with public permission and exists by public approval.”

In this sense, public permission and approval are also the prerequisites for the chemical industry and its business.

One of the biggest problems facing the chemical industry today is the bad name the industry has with the public in general. This is mainly based on misconceptions which the chemical industry has failed to clear up with the public. On the other hand, there were also reasons in the early days when industry was acting on the basis of a regulatory driven approach to environmental management and, in the 1970s, also to chemical safety.

These approaches have changed. The industry started 15-20 years ago to adopt more pro-active approaches to environmental management systems and chemical safety.

There are a number of issues reflecting fundamental changes in the “environmental and human health and safety philosophy” of the chemical industry, such as:

- improvement of process management
- pollution prevention
- waste reduction
- new chemicals/products.

In the end, these developments lead to Responsible Care (RC).

RC is a voluntary process in which the chemical industry commits itself to address matters relating to the safety, health and environment of their production facilities.

Safety, health and environment apply to product performance, recycling and disposal. In order to achieve this goal, interaction and relationships have to be established with:

- employees
- customers
- suppliers
- the community.

RC is most useful to prevent the hazardous effects and reduce the risks associated with chemicals. For the chemical industry, risk assessment and communication as elements of risk management are critical activities, because the properties that make our products useful to society are often combined with properties that make them hazardous and require careful controls.

Risk management under RC also means identifying the most cost-effective risk reduction measures, based on an analysis of socio-economic aspects, in order to protect human health and the environment.

From industry's viewpoint, risk management decision making aimed at reducing/eliminating identified risks should also, in an international/global context, be:

- based on the best available scientific, economic and other technical information
- feasible, with benefits reasonably related to costs
- sensitive to political, legal, social and cultural conditions/considerations.

It is industry's strong belief that, in addition to risk assessment, the analysis of socio-economic aspects has to play an important role in the risk management framework, because regulatory chemical management activities are increasingly targeted on the development and implementation of international/global legally binding instruments.

There is still a controversial discussion on the value, strengths, limitations and uncertainties of the analysis of socio-economic aspects and its role in regulatory risk management decision making.

This paper provides the view of the international chemical industry on some aspects, as well as presenting the role of socio-economic analysis as integral to the risk management of chemicals.

It is industry's clear view that the analysis of socio-economic aspects is a legitimate and useful way to obtain information for sound risk management, and that it can contribute to making better use of society's limited resources.

Both risk assessment and CBA contribute to and determine regulatory risk management decisions. They have to play complementary roles.

Whenever measures to reduce the risks of an activity or a chemical are considered, the costs of the measures and alternative solutions, as well as their comparison with the expected benefit, have to be analysed.

A CBA must take account of technical and economic information as well as certain welfare and social aspects. This means that CBA relies on values, precise information, assumptions, extrapolations, uncertainties and judgement. Results of a CBA cannot be interpreted precisely. Uncertainties in the outcome have to be identified and communicated.

Therefore, peer review has to play an important and critical role in evaluating both the quality of a CBA and the available information. The analysis needs to show the advantages and disadvantages that would result from the realisation or non-realisation of a measure for all those who are affected by it. The final aim of any CBA is to identify the most efficient and cost-effective risk reduction option.

A CBA should be as transparent as possible; it should not be a lengthy, detailed, over-demanding process which turns out to be unworkable in practice.

Information about costs and benefits that are intangible and that cannot be assigned monetary values, or even expressed in quantitative terms, should be addressed and considered explicitly in a qualitative analysis.

The CBA should provide a decision making basis that can be objectively checked by all stakeholders. It should be documented in such a way that it allows the subsequent adjustment of measures to achieve the objectives in cases where the data underlying the analysis have changed.

The following example describes the efforts of the chemical industry in regard to risk management of pesticides at a certain stage of their life cycle: i.e. the management of pesticide containers.

The UNEP Governing Council's 19th session in January 1997 decided that there was a need for further international work in regard to obsolete chemicals and pesticides and their wastes, in particular in developing countries.

What about the situation?

Example: Colombia/Argentina

Colombia

- Colombia is the fourth most important consumer of pesticides in Latin America.
- Colombia has great influence on the Andean Pact countries through its leadership in the harmonisation of the pesticide legislation.
- The Department of Environment is developing legislation that will prohibit burning and burying in the field and will demand the collection of empty containers and their final disposal by incineration or recycling.
- High pressure from environmental groups.
- 31% of Colombia's containers are distributed in the area of Cundinamarca-Boyacá.
- Cold climate crops: predominance of small farmsteads.
- Low literacy level.
- The largest portion of consumed containers consists of plastic bags and small containers (smaller than one gallon).
- There are no farmers organisations or agricultural federations with real response capacity in regard to conflicts with the government.
- Cement kilns in the area.

Argentina

- Planted area: 30 million ha
- Total number of farmers: 400,000
- Sales points: 4000
- Mkt. (US\$): 800 million
- Mkt. (tons): 100 million
- Product Consumption: 3.3 kg/ha
- Avg. distance between towns: 30 km
- Total number of containers: 13 million (5500 tons or 0.44 containers/ha)

Cultural factors

- Educational limitations
- Triple rinsing: most users do not do it (lack of consciousness)

Economic factors

- Low disposition to pay to clean the environment
- Any solution will demand high investment and expenses

Two options for environmentally sound management of pesticide containers were identified:

1. Recycling
2. Energy recovery

An analysis shows the following:

1. Recycling

- New agrochemical containers
- Other plastic products (benches, fences, etc.)
- Contacts were made with two companies: preliminary interest detected

ADVANTAGES

- Quick to implement
- Available partners

DISADVANTAGES

- The problem is not entirely eliminated (residues)
- Technical problems (emissions, lack of triple rinsing, etc.)

2. Energy Recovery

- Cement kilns
- Contacts made with leading companies (locally)
- International contacts could reactivate negotiations

ADVANTAGES

- Ideal technical solution (environmentally friendly)
- Headquarters pressure (Holderbank)

DISADVANTAGES

- Not feasible legally (today)
- Unwillingness/reluctance of local cement subsidiaries (environmental pressure)

Perceived by cement plants not as energy saving but as a business opportunity (charging for incineration services)

Pirolitic kilns/incineration:

- Technically perfect
- Ready available
- High cost: US\$ 1000/ton (not considering collection or transportation)

Steel plants:

- Technology for alternative fuels not currently available in Argentina (plastics)
- No interest by steel industry in our scrap metal

Action steps:

- Define best alternative
 - CASAFE recommends energy recovery in cement kilns:
 - ◊ Develop a legal framework
 - ◊ Logistics/collection (a site/distributor already available)
 - ◊ Close a deal with cement companies
- Less desirable: plastic recycling
 - In case the cement alternative fails
 - Take advantage of interested recycling companies
- Continue to strengthen cooperation with government
- Continue the triple rinsing campaign

What are the costs of the project in Colombia/Guatemala?

Budget

• Hiring of a technician to execute the project (salary/year)	US\$ 12,000
• Incentives to the farmer (protection & aspersion equipment, etc.)	US\$ 2,000
• Cost of 3 mills (2 mobile, 1 fixed)	US\$ 6,000
• Collection site/year	US\$ 12,000
• Transport collection site - cement kiln/year	US\$ 8,000
• TOTAL	US\$ 40,000

AND I will be responsible for all other aspects, such as administration, security and controlling, the materials and campaigns to make the project public, the arrangements with the government and possible contingencies.

Budget in US\$

	1998	1999	2000	2001	2002
Hammer mill	5,000	5,000	5,000		
Mill technicians	10,000	20,000	30,000	30,000	30,000
Mill fuel	1,000	2,000	2,000	2,000	2,000
Container transport	1,000	2,000	2,000	2,000	2,000
Advertising	10,000	10,000	10,000	10,000	10,000
Contingencies	3,000	1,000	1,000	1,000	1,000
TOTAL	30,000	40,000	50,000	45,000	45,000
Collection sites	2	3	4	4	4
Expected tonnage to be collected	25 MT	35 MT	45 MT	60 MT	80 MT

With this project they are planning:

- to install 4 collection sites
- 34 direct customers
- to keep the present 8 banana companies as customers

Conclusion

While risk-benefit analysis of an activity or a chemical resulting in recommendations for risk reduction measures is usually only done in qualitative terms, the analysis of the cost of the measures and alternative solutions can mostly be done in quantitative monetary terms. When compared with the benefits, this allows selection of the most cost-efficient alternative.

The implementation of the analysis of socio-economic aspects in the risk management framework does not mean that regulatory decisions about health and environmental protection might be made strictly on the basis of whether their quantifiable benefits outweigh their monetized, quantifiable cost.

It is industry's clear view that the outcome of a socio-economic, cost-benefit analysis contributes only part of the information that must be considered in making decisions about the best ways to protect human health and the environment. However, CBA can contribute to making better and more efficient use of society's limited resources globally.

Using Economic Analysis as a Tool for Evaluating Risk Management Alternatives: Case Studies in Lead

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Lead has many uses because of its properties. As a result, it is a well-known and well-used chemical, and is found throughout the environment. Unfortunately, many human health and environmental risks result from exposure to this substance. The United States Environmental Protection Agency (EPA) has identified lead as a National Program Chemical and is committed to addressing risks related to lead in the environment. Because of lead's widespread presence in the environment, management of lead risks is a daunting task. Therefore, the EPA's management of lead risks requires thoughtful decision making.

When considering chemical risk management policies, the EPA evaluates many factors including risks, economic effects, and resource, statutory, and legal constraints. Economic analysis provides direct support to the decision making process in several areas. In the two examples presented in this paper, the role and use of economic analysis is highlighted.

The first example, related to the management of chemical risks associated with lead-acid batteries, illustrates the use of economic analysis to frame the problem under consideration. It shows how economic information is useful for defining the scope of the problem and narrowing the focus for risk assessment. The economic analysis can also help in the development of risk management options.

The second example reviews the use of economic analysis in the evaluation of strategies designed to manage risks associated with lead abatement in homes and external structures. In particular, the case illustrates the interrelationship between risk assessment and benefits analysis. It shows how economics can provide additional interpretation of risk information by monetizing risk reduction. The case also explicitly illustrates the divergence between the text book interpretation of cost-benefit analysis and cost-benefit analysis as conducted without complete information. Instead of abandoning the use of cost-benefit analysis, it demonstrates the use of qualitative factors and the craft of converting available data into information useful to the decision maker.

Example 1: Lead (Pb) Acid Battery Recycling

Background: Problem

In the early 1990s, the EPA had concerns that focused on the lead-acid battery market and the recycling of lead-acid batteries. Lead markets in general, and lead-acid battery markets in particular, were subject to several failures that led to suboptimal private sector decision making concerning lead production, consumption, and disposal/reuse. First, disposal of lead-containing products, including lead-acid batteries, was believed to pose risks to the public, environment, and workers. Full consideration of these risks by those disposing of these products is unlikely. Also, due to the difficulties of detecting and enforcing prohibitions against inappropriate disposal of lead and lead-acid batteries, any existing provisions of the federal and state laws and regulations, intended to address these issues, were not thought to function efficiently. For these reasons, the EPA considered rule making to correct the potential market failures.

Economics played a major role in the rule making from the beginning of the risk management process. Economic information was provided to EPA decision makers, the public (industry and special interest groups were involved as this was a negotiated rule), and health, exposure, and risk assessment scientists within the EPA to help characterize the issues and formulate potential solutions.

Economic Analysis

Understanding the Issue

A market analysis examined the battery chain of commerce, from the mining of primary lead through the manufacture, use, recycling, and disposal of batteries. Detailed information was obtained on both the lead mining and recycling industries, including size and location of mines and facilities, production output, historical market trends, sources and types of lead scrap, capacities for domestic and international lead mining, recycling, refining, and import/export markets of the U.S. Also considered were prices and the battery market. Knowledge of the life cycle of batteries, including when they were collected and disposed, and the economic conditions affecting recycling and disposal choices further clarified the dynamics of the market.

The economic analysis identified the existence of an established market for battery recycling at secondary smelters but showed that, even with the market system in place, not all batteries were recycled. Three general reasons for this occurrence were identified. First, despite the technical feasibility of recycling, there were economic and other reasons that batteries were not recycled, including retailer reluctance to accept them. Second, technical constraints and information problems limited current recycling of batteries contained in products. Third, the demand for secondary (recycled) lead was not always high enough to exhaust the supply of available scrap batteries. For example, when demand for lead is low, supplies of both primary and secondary lead fall, implying a reduction in the recycling rate for scrap batteries. This information suggested that to maximize recycling effort, the market must be encouraged to reduce the use of primary lead before the supply of secondary lead would be used.

The market analysis also identified three major areas where lead-acid battery recycling was problematic: 1) starting, lighting, and ignition (SLI) batteries that are not recycled regardless of market condition, 2) consumer lead-acid batteries contained in products for which a recycling technology may not presently exist or whose users may not be aware of the presence of the batteries, and 3) the less-than-desirable rate of scrap battery recycling due to either the tendency to minimize costs and rely on primary, rather than secondary, lead when lead demand is low, or an increase in scrap batteries available compared with the demand for secondary lead.

Options Development

Using the information from the market analysis, the EPA developed various approaches to address the areas where lead-acid battery recycling was problematic. One approach attempted to address the lead-acid battery disposal problem by ensuring that the return of lead-acid batteries for recycling would be simple and not impeded by retailer or others reluctance to accept them for recycling. A second approach established market-based incentives for secondary smelters that would translate directly into reduced disposal of lead-acid batteries. Together, these two approaches encouraged additional secondary lead production through greater lead-acid battery recycling, reducing market failures related to disposal. This would also reduce the total primary lead produced over time as secondary lead production increased. Because primary lead production is the initial source of human and environmental exposures to lead, the approaches were also expected to reduce the risks related to those exposures over time.

The EPA developed five basic risk management options:

1. Mandatory take back -- prohibits disposal of lead-acid batteries in municipal waste landfills; requires battery retailers, distributors, manufacturers, and secondary smelters to accept spent batteries; requires record keeping and reporting.
2. Mandatory take back with a deposit instead of trade-in -- beyond the requirements of the mandatory take back option, imposes a fee on battery purchasers who do not turn in a scrap battery at time of sale;
3. Minimum secondary lead content -- mandates a minimum secondary lead content percentage of lead used to manufacture batteries;
4. Fee on lead in batteries with rebate for secondary content -- collects a single fee for all lead used in battery manufacturing and offers rebates for demonstrated secondary content; and
5. Fee on primary lead in batteries (exemption for secondary) -- collects a single fee on all primary lead used in battery manufacturing (exempts secondary lead used in battery production for the fee).

Several of these options are considered economic incentives and work by harnessing the forces of the market to achieve the desired level of lead-acid battery recycling and risk reduction. The market analysis identified these as options likely to effect the desired changes.

Cost-benefit Analysis

The EPA conducted an initial economic analysis of costs and benefits to learn which option would most increase the recycling rate and reduce risks for the least cost. The analysis of costs and benefits are discussed separately below.

Costs

The goals of the cost analysis were to define and measure the net social costs, to identify the economic entities who bear the costs imposed by the regulatory alternatives, and to set the respective fees that need to be charged to increase recycling of lead-acid batteries.

To estimate the costs (and benefits), the economist needs to develop an understanding of how the option will affect markets. The options that impose fees on lead in batteries are economic incentives and change the battery market by making the use of (primary) lead more costly. For example, a fee on primary lead used in manufacturing batteries makes the use of primary lead more expensive. Because use of secondary lead is not subject to the fee, this increases the demand for secondary lead for use in batteries. This increased demand implies that the supply of secondary lead increases and its price will rise. Higher secondary lead prices imply higher scrap prices, which may induce additional scrap collection or depletion of scrap battery stocks, and increase battery recycling. Thus, primary lead production is expected to fall and secondary lead production (through recycling) is expected to rise. The economic analysis developed a model that incorporated knowledge of the national and international markets to learn how various fee levels would affect supply and demand of primary and secondary lead.

Alternatively, the EPA considered a mandatory minimum recycled content standard in a single year. This standard directly sets a floor on secondary lead used in batteries. The intent of this standard is to provide a positive incentive for secondary lead production at times when market forces dictate a fall in the recycled content of batteries. If binding, the mandatory minimum recycled content standard increases the demand for secondary lead for use in batteries. Battery manufacturers will compete for secondary lead and increase the price of secondary above the price of primary lead. If the recycled content standard is set

at historical levels, it implicitly “grandfathers” the existing primary lead content in batteries. As with a fee, production and recycling of secondary lead increases, and a shift to primary lead in the production of lead-containing products, excluding batteries occurs. Again, the economic analysis provided the information that determined how the recycled content would ultimately change the supply and demand for primary and secondary lead.

Take back requirements for retailers, distributors, battery manufacturers, and secondary smelters concerning scrap batteries were another option considered by the EPA. They are intended to increase collection and recycling of scrap batteries. With this increase in secondary lead supply, lead prices will decrease and less primary lead will be supplied. For example, consider an increase in the price of secondary lead and a decrease in the price of primary lead used by non-battery manufacturers resulting from a fee on primary lead in batteries. Battery producers pay a higher price for all lead they use, and so they, and the purchasers of the batteries, experience losses. Producers of other lead-containing products (and their customers) experience gains because they pay lower prices for lead. Losses in production occur for primary smelters, who receive a lower price for the lead that they sell. The rise in the price of secondary lead results in producer gains that may be realized by secondary smelters, or by the owners of the scrap batteries used in the production process.

Intuitively, the mandatory minimum lead recycled content in batteries and fee-related options impose costs on society. As illustrated by the market changes described above, lead is supplied through a different, and more expensive, combination of sources than would occur without the regulatory options. These are the costs considered in the economic analysis.

Benefits

The benefits of this rule result from reducing exposures to lead from lead smelting and the incineration of batteries disposed in municipal solid waste facilities. The approach for estimating benefits was based on an assessment of populations exposed to lead from these activities. Populations at risk and the exposures that were analysed included exposures to municipal waste incinerator operators and ash handlers, and ambient exposures to children living near smelting facilities and municipal waste incinerators. By increasing the rate of recycling of lead-acid batteries, the amount of lead in municipal waste incinerators (MWI) will decline, reducing both direct and indirect exposures to lead from this source. The increase in recycling of lead-acid batteries reduces direct exposures to MWI workers and indirect exposures from municipal solid waste incinerators. However, increasing the rate of recycling for lead-acid batteries increases how much lead is processed by secondary smelters and increases ambient exposures. Economic values estimated for the health effects were used to compare against the costs and identify which option would be the best.

The economic analysis contributed to many components of the rule making analysis and decision making process for lead-acid battery recycling. The market analysis provided information that helped focus the problem by identifying the structure of the lead-acid battery and overall recycling market. The economic analysis was crucial in constructing options that could be used to promote recycling of lead-acid batteries and was used frequently to explain the problem and proposed solutions to the public, affected industry and special interest groups. The identification of location and production volume of lead processing and recycling facilities allowed the risk assessors to more accurately assess risks to populations near the smelters. The economic analysis also provided information that identified the appropriate economic incentives that would be required to achieve different levels of lead recycling rates. The analysis of costs and benefits provided information to the decision makers on how different options compared regarding benefits achieved and costs imposed. In the end, the economic and risk analyses revealed proposed government intervention to increase the recycling rate from already high levels to higher levels was not desirable. The analyses showed that the costs imposed on society by the proposed intervention were greater than the risk reduction benefits achieved. A final report on the benefits was, therefore, not

produced. Due to the results provided by these analyses, the EPA refocused its resources toward other lead related issues.

Example 2: TSCA Title IV, Sections 402(a) and 404: Target Housing and Child-Occupied Facilities Final Rule

Background: Problem

Exposure to lead-based paint hazards elevates blood-lead levels and results in adverse health effects, especially in young children less than seven years of age. The lack of lead-based paint abatement, or improperly conducted abatement activities will elevate blood-lead levels. In response to continuing concerns about lead poisoning among American children, Congress amended the Housing and Community Development Act of 1992 to include Title X: the Residential Lead-Based Paint Hazard Reduction Act of 1992. Title X amended several existing housing, worker safety, and environmental regulations, and added Title IV: Lead Exposure Reductions to the Toxic Substances Control Act (TSCA).

Provisions under §402(a) of Title IV require the proper training of all individuals engaged in lead-based paint abatement activities, accreditation of training programs, and certification of contracting firms that conduct lead-based paint activities. Section 404 authorizes states to administer and enforce their own lead-based paint programs, which shall be “as protective” as the EPA’s Federal program under §402(a). Section 404 also requires the EPA to develop a model program that may be adopted by states who choose not to develop their own programs. As part of the rule making decision process, the EPA analysed the costs and benefits of the requirements of §§402(a)/404.

Economic Analysis

Understanding the Issue

In framing its economic analysis, the EPA economist identified the benefits and costs that were likely to result from an Agency action. Understanding these factors helped the development of the analysis by identifying pertinent issues and providing the proper focus.

Costs

The costs of the regulation are based on the number of lead-based paint activities that will occur following promulgation of the rule and the future demand for trained and certified personnel. The costs fall into three categories: costs resulting from the training and certification requirements for lead-based paint inspection, risk assessment, and abatement personnel; costs resulting from the imposition of reliable, effective, and safe work practice standards for performing lead-based paint activities; and costs of establishing and operating State, Indian Tribe, or Federal programs to administer, monitor, and enforce the standards, regulations, and other requirements established under §§402/404.

Benefits

Avoiding lead-based paint hazards helps assure a low blood-lead level and avoids associated health problems. High blood-lead levels in young children often lead to developmental problems resulting in decrements in IQ. The economic consequences of this reduced IQ may result in lower lifetime earning potential and special education needs; avoidance of these effects can be interpreted as a benefit to the

individual, and therefore to society. Presumably, a quality of life benefit for the individual also exists. Capturing the value of this element poses a major challenge and the EPA did not address it in its analysis.

Additional benefits result from avoiding elevated blood-lead levels in adults. Research suggests that elevated blood pressure, resulting from high blood-lead levels, can increase the incidence of heart attacks and strokes. Studies have also linked high blood-lead levels of expectant mothers to low birth rates and greater infant mortality rates. Avoiding these health endpoints will result in significant health care costs savings.

A third category of potential benefits is the reduction in ecological damage from lead exposure that would result from adherence to work performance standards during lead-based paint abatements. Studies have shown negative impacts to both flora and fauna associated with excessive lead loadings.

Cost-benefit Analysis

Theoretical Approach

The text book approach for evaluating the rule is to compare marginal benefits with marginal costs, i.e., the incremental benefits resulting from a decrease in risk to human health and the environment to the incremental costs of bringing this decrease about. Furthermore, the analysis must consider those marginal benefits and marginal costs that occur with and without the rule. Without the proposed rule, lead abatements would continue to occur with the attendant set of benefits and costs. After promulgation of the rule, a presumably different set of benefits and costs would occur. The comparison of with and without rule benefits to the with and without rule costs is the marginal analysis that should ideally be conducted.

Using children's health effects as an example shows this approach. As posited, exposure to lead-based paint hazards results in unwanted health impacts to young children. The desired result of the rule is to reduce lead-based paint hazards by ensuring that those involved in abatement are properly trained. When abatements are attempted by untrained individuals, the results may not reduce the lead hazard, but may, in fact, exacerbate it. This occurs from not employing proper safeguards to isolate residents from the elevated dust levels that accompany abatements, e.g., special precautions such as vacuuming and wet mopping will help control these by-products of abatement. This difference in abatement efficiency represents the basis of the rule's benefits: the avoidance of lead hazard results in avoidance of high blood-lead levels and decrements in IQ, which translates to higher lifetime earning potential and avoided special education costs.

The cost categories of this rule have been identified above. Section 402 training and inspection costs include the opportunity cost for the time spent training, course costs, travel costs, and per diem. Accreditation costs include evaluation of course providers to insure their competence and evaluation of course content. Work practice standards generate costs by requiring adherence to more rigid abatement standards, more sophisticated on-site testing for the presence of lead, and laboratory tests. Section 404 costs include the program administration and enforcement costs.

Even without the rule, costs may still exist. For example, some contractors currently provide their own in-house training, and several states have lead-based paint abatement legislation of their own. These existing conditions provide a baseline of costs that must be taken into consideration when estimating the incremental costs of the rule.

"Real World" Approach: Flexibility and Innovation

The with and without marginal analysis described above requires the existence of the relevant data and models. Generally, these are more readily available for the cost estimates than for the benefit estimates. Typically, cost estimates are based upon observable market transactions that can be used

directly to estimate values. On the other hand, benefits are often “nonmarket” goods, e.g., they are not bought and sold on the open market. Therefore, the argument made for this rule is that the reduction in lead paint hazards will avoid elevated blood-lead levels that will avoid decrements in IQ points. IQ points are not, of course, a marketed good; therefore, it is necessary to place a value on this “commodity.” This series of linkages requires several models: a model that translates lead exposure to blood-lead levels; a model that estimates impacts of blood-lead loadings on IQ; and finally, a model that relates IQ to lifetime earning potential. The EPA designed the Integrated Exposure Uptake and Biokinetic model to estimate the distribution of blood-lead levels for children exposed to environmental concentrations of lead in air, water, diet, soil, and household dust. A literature search provided the remaining links.

The estimate of IQ as a function of blood-lead levels was obtained using a dose-response relationship of 0.25 points per $\mu\text{g}/\text{dL}$ of blood lead. Research findings revealed that the impact of IQ on lifetime earnings could be divided into two parts: direct and indirect effects. Higher IQ levels translate directly into higher lifetime earnings. They also translate indirectly by leading to higher educational achievement and greater labour force participation levels that also result in higher lifetime earnings. Combining the direct effect of 0.5 percent of lifetime earnings per IQ point with the two indirect effects (0.786 percent for more schooling and 0.477 percent for greater labour force participation) yields a total impact of 1.76 percent on lifetime earnings per IQ point. Average lifetime earnings estimates, based upon U.S. Department of Commerce publications, provide the basis for monetizing an IQ point. U.S. Department of Education publications provided the necessary information for special education costs estimates.

The availability of the models described above provides the necessary, but not sufficient conditions for the estimation of the marginal benefits of this rule. The analyst also requires information to ascertain the lead risk abatement efficacy of the trained abater vis-à-vis the untrained abater. It is presumed that abatements performed by trained abaters result in young children having acceptable blood-lead levels, i.e., $10\mu\text{g}/\text{dL}$. Although anecdotal information suggests that effectiveness of abatements currently being performed by untrained abaters is questionable, there does not exist a data source to confirm this assertion.

This absence of information, contrasting the deleading efficiency of trained and untrained lead abaters, did not allow for the comparison of incremental benefits and costs to ascertain whether net benefits would be positive or negative. However, a considerable volume of information, models, and studies do support the concern over lead-based paint risks. Thus, the EPA analyst developed an alternative approach for examining the economic consequences of this rule. The analyst compared an estimate of total benefits to an estimate of incremental costs. This approach argues that if the incremental costs of the rule are a significantly small percentage of total benefits, then it is reasonable to conclude that the incremental benefits of the rule are likely to outweigh them. For this rule making the total measured benefits, for both target housing and child-occupied facilities, are approximately \$16 billion, nearly 17 times the incremental costs of \$960 million. In other words, if only 6 percent of the total estimated benefits are actually attributable to this rule, it is reasonable to conclude that the §§402/404 rule will provide positive net benefits.

The foregoing demonstrates that even in the absence of all the necessary and sufficient information and models, the innovative economist can still provide valuable information for the decision maker to make an informed decision.

Conclusion

These cases illustrate the particular insights that economic analysis can impart to the risk management decision making process. Such information can uniquely supplement the information that can be considered by the risk manager throughout the risk management process. Market studies and general

identification of the benefits and costs of risk management can help to characterize the problem at hand, provide some guidance on the development of viable options, and generally help to focus the problem and necessary analytical work. Cost-benefit analysis is useful for comparing the effects of alternative risk management strategies.

It is also clear that the information or models required to complete comprehensive cost-benefit analyses are often absent. In fact, this is more often the case than not. However, this is not a cause for abandoning the use of this type of analysis. Information can still be developed and interpreted by the economist so that it can inform the decision making process. This is, after all, the goal of the economic analysis of policy.

Incorporating Economic Analysis in Environmental Policy Making: The UK Experience

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Introduction

Since the early 1990s, there has been steady progress in the UK in developing, applying and refining policy appraisal techniques. This paper considers the nature and development of a framework for policy appraisal in the UK, and provides specific examples of the way in which this framework has been applied in practice.

Appraisal can be defined as the process of defining and examining options, and of explicitly assessing the costs and benefits of actions, as an integral part of the decision making process. Of relevance to this workshop are two distinct dimensions to appraisal: **the application of economic analysis to the design of environmental policy, and the incorporation of environmental considerations into other policy areas** - for example, into transport, industrial and agricultural policy areas. The concept of sustainable development is one that should encapsulate both of these dimensions of appraisal. In the UK, the recent merger of the two government departments of environment and transport, to form the Department of the Environment, Transport and the Regions (DETR) can be seen as an important opportunity to ensure that an integrated approach is adopted with respect to the development of transport and environmental policies. This move also reflects the new administration's commitment to putting the environment at the heart of decision making. The "Integrated Transport Policy" (New Deal for Transport: Better for Everyone; White Paper on the Future of Transport), published in July 1998, confirms this commitment.

Guidance Provided by Government Departments in Carrying Out Policy Appraisals

The following are key guidance documents on policy appraisal produced in recent years by a number of different UK government departments:

- *Economic Appraisal in Central Government - A Technical Guide for Government Departments - "The Green Book"* (HMT, 1991); updated: *Appraisal and Evaluation in Central Government* (HMT, 1997);
- *Policy Appraisal and the Environment* (DoE, 1991);
- *Environmental Appraisal in Government Departments* (DoE, 1994);
- *A Guide to Risk Assessment and Risk Management for Environmental Protection* (DoE, 1995); and
- *Experience with the "Policy Appraisal and the Environment" Initiative* (DETR, 1997).

"The Green Book" covers the technical appraisal framework and is aimed at ensuring a systematic, consistent and effective approach for both appraising policy options ex ante, and evaluating decision making ex post. Both the basic principles, and the broader technical issues - for example, use of

discounting and treatment of risk and uncertainty - are covered. The Green Book falls into the first of the two categories flagged up in paragraph 2 above, i.e. the application of economic analysis to policy decisions.

Policy Appraisal and the Environment (PAE), on the other hand, relates to the second strand: ensuring that environmental considerations are fully integrated into the decision making framework. The key message here is that for a thorough and consistent appraisal of policy, all relevant implications, or outcomes, of policy options should be taken into account, not just the direct financial implications.

Environmental Appraisal in Government Departments (EAGD) is a follow-up to PAE, providing further guidance on environmental appraisal through the experience provided by case studies. These cover a wide range of areas, from agriculture to transport to hazardous chemicals, which were selected as a representative cross section of the work that is being done by and for government departments; and impacting on all three environmental media.

A Guide to Risk Assessment and Risk Management for Environmental Protection explores some of the underlying principles of assessing environmental risks and expands on aspects of PAE and EAGD.

All of the above guidance documents are available through HMSO - see reference section at the end.

Mechanisms for Incorporating Environmental Analysis in UK Policy Making

Efforts to stimulate the widespread take-up of the advice included in the series of guidance documents have taken a number of forms, which have included the appointment of "green ministers" throughout Whitehall and the establishment of an interdepartmental Group on Environmental Costs and Benefits (GECB). Economists from all major departments are represented on this group, which meets roughly twice a year. Its role is to ensure that guidance, such as that provided in PAE, is systematically applied throughout government.

To this end, the group recently commissioned external consultants, KPMG, to evaluate the experience with PAE. This culminated in the recent release of the study report, *Experience with the "Policy Appraisal and the Environment" Initiative*. Conclusions were based on the experience from 19 case study appraisals covering policies over the period 1986 to 1989. A major finding was that government departments were conducting policy appraisals along the lines recommended in PAE, but that the framework was not being systematically applied. The consultants report a continuing reluctance by departments to whole-heartedly embrace two of the main types of economic techniques which could be applied, monetary valuation of environmental costs and benefits, and multi-attribute techniques. In the case of the first, resource, time and methodological concerns have not been fully overcome. In the case of the second, which includes simple decision matrices or scoring and weighting systems, there continues to be infrequent use by policy makers, despite the attraction of setting out a transparent framework under this approach.

KPMG's recommendations include:

- "DoE should design a short aide-memoire which reminds officials of the potential importance of the environmental impacts of their policies and what steps they need to go through to consider the environment. The guidance should be targeted at officials who have operational policy responsibilities and must direct users to sources of expertise in the environment and its appraisal."
- "For officials who undertake or commission detailed policy appraisals, the DOE should champion the use of best practice techniques, using the GECB as a discussion forum. The DoE should consider drawing together case studies using

both written material and seminars. It should also investigate the potential for a review of the existing literature on monetary valuation techniques including a survey of empirical studies.”

The pushing forward with work on valuation techniques represents a continuation of one of the GECB’s main roles to date. The group has, for example, been proactive in the area of valuing the health impacts of air pollution. In November 1995, a one-day workshop was held to discuss the state of knowledge in this field; government and academic economists, air pollution scientists and medical experts participated. As a follow-up, a study was commissioned, with a remit to produce “a think-piece describing a robust, economically-sound but pragmatic approach to the valuation of air pollution mortality effects, taking into consideration approaches to the valuation of statistical life in other contexts.” The report - *Valuation of Deaths from Air Pollution* - was released in February 1998 through the consultants, NERA (National Economic Research Associates). Further work on the economic appraisal of the health effects of air pollution, both mortality and morbidity effects, is being taken forward in a new expert group commissioned by the Department of Health, the Group on the Economic Appraisal of the Health Effects of Air Pollution (EAHEAP).

The GECB also reviewed a literature survey on the valuation of environmental externalities which was completed for the Department of Transport in April 1995 and which has become known by the name of its author, the “Tinch” report. The report provides a very useful overview of the methodologies for valuing externalities - hedonic price methods, travel cost method, contingent valuation techniques, conjoint analysis and dose-response techniques - which is followed by a systematic review of progress by impact category - noise, air pollution, global warming, vibration, and other effects such as water pollution and visual intrusion. The report concludes that important advances have been made in recent years, but that major uncertainties and gaps remain.

Cost-Benefit Analysis of Environmental Policy in the UK

Until recently, government departments in the UK have been required to submit to Parliament a risk and compliance cost assessment for all new regulations to be laid. However, new draft guidance has been circulated by the “Better Regulation Unit” in the Cabinet Office on the new exercise of “Regulatory Appraisal”. The new requirements bring together the two sides of the assessment exercise - the costs and risk assessments - and aims to go further than the narrow compliance cost assessment exercise, by considering cost impacts beyond those imposed directly on businesses; for example, account now has to be taken of the impact on consumers and on the economy more broadly.

In the DETR, economic advice is provided to environmental policy makers on a media by media basis. On the ambient air side, the key new policy initiative is the National Air Quality Strategy (NAQS) which was published in March 1997. This policy document sets ambient air quality objectives, to be achieved by 2005, for eight air pollutants: benzene, 1,3 butadiene, carbon monoxide, lead, nitrogen dioxide, ozone, fine particles and sulphur dioxide. The section of the Strategy which covers the setting of standards and objectives concludes:

“Standards and objectives relating to air quality are the fulcrum of this Strategy. The fundamental aim of Government air quality policy is to render polluting emissions harmless, and a strategy to achieve this aim needs to define the level of harmlessness, and then to direct its policy towards the achievement of those levels by means of objectives **as costs and benefits dictate.**”

The two annexes to the Strategy summarise the relevant studies and data available on the costs and benefits associated with the objectives. A commitment is also made to improving on the estimates currently available. This is being taken forward by an interdepartmental group of economists, set up to inform the first review of the Strategy which is to be completed by the end of 1998.

The starting point for the economic evaluation of the air quality objectives is the firming up of the compliance gap, i.e. estimating the likely degree of exceedance of the objectives by 2005, given the current and agreed policies which have been/will be implemented regardless of the Strategy being in place, i.e. the “baseline”. The economists’ role is then to derive, as far as this is possible, annualised costs and benefits for measures needed to close any gap that exists, on a pollutant-by-pollutant basis. It is unlikely that all the relevant benefits will be quantifiable in monetary terms, and therefore a semi-quantified or qualitative approach should be applied to such impacts. This is consistent with ensuring that the cost-benefit framework is comprehensive and as transparent as possible, including all the relevant benefits (as well as costs), and not omitting those for which full monetisation is not currently feasible.

Turning to the waste side, the recent introduction of the landfill tax provides a good example of the way in which the valuation of externalities can play an important part in policy formulation. The Department of Environment had commissioned the Centre for Social and Economic Research on the Global Environment (CSERGE) to produce monetary estimates for the main externalities associated with the use of landfill for the disposal of waste. The report, *Externalities from Landfill and Incineration*, published in 1993, provided impetus for the introduction of the market-based instrument as a means of internalising the externalities associated with landfill.

On the water side, work has been commissioned by the Environment Agency to develop a Manual for assessing the benefits of improved surface water quality. The manual provides a benefit transfer approach to valuing water quality, but is constrained by the limited nature of the studies which it collates. The Agency is currently exploring how to use the Manual and other techniques, including scoring and weighting schemes for developing its water quality objectives, and its proposed National Water Plan.

EU Policy and UN-ECE Transboundary Protocols

At the European Commission level, a “*fiche d’impact*” should be completed for any new policy initiatives, and should include an assessment of the relevant costs and benefits. In practice, however, it is not clear that these are completed in a consistent way, and there is no clear specification of what should be covered by the *fiche d’impact* on a dossier.

To inform the UK position on new EU environmental policy initiatives, Government economists provide advice to UK policy makers on the likely costs and benefits ensuing from implementation of the policy: on the benefits side, this may stop at the quantification of physical impacts, if it is regarded as too uncertain to assign monetary values. A recent example of the application of economic analysis to an EU policy proposal was a consultancy study commissioned by the DETR into the likely cost implications, for the UK, of the proposed EC Directive on the Sulphur Content of Liquid Fuels.

The UK takes a leading role in the various working groups and task forces which operate under the auspices of the United Nations Economic Commission for Europe (UN-ECE) Convention on Long Range Transboundary Air Pollution (CLRTAP). The Task Force on the Economic Aspects of Abatement Strategies (TFEAAS), chaired by Professor David Pearce, is currently charged with advising the policy making body, known as the Working Group on Strategies, on the size of the benefits associated with various abatement scenarios. Currently, preparatory work is being carried out on the proposed “Multi-Pollutant, Multi-Effect Protocol” which is to cover the three pollutants: nitrogen dioxide, volatile organic compounds and ammonia. To this end, a consultancy study, commissioned by the UK DETR, is shortly to report on the likely value of benefits associated with two abatement scenarios. The benefit impacts covered include those on health, buildings and materials, crops, and natural ecosystems. Together with the data on the associated costs of abatement, these estimates will help to inform policy makers’ decisions on the appropriate level of reductions to sign up to in the forthcoming protocol.

Cost-Effectiveness Analysis

It is often not possible to carry out a full cost-benefit analysis of environmental policy proposals, and where firm commitments have been made to achieving pre-determined targets, then cost-effectiveness analysis tends to be a favoured technique for ensuring that scarce resources are allocated as optimally as is possible, given the set target.

Climate change policy provides an obvious example of where the cost-effectiveness approach has a particular appeal, given the very large uncertainties associated with the valuing of the benefits of abating or mitigating greenhouse gas emissions. In the UK, as elsewhere, preparations for the Conference of the Parties in Kyoto have included the systematic review of the costs of a wide range of alternative policy instruments for delivering greenhouse gas reduction, as an important contribution to informing the party's negotiating stance.

Concluding Comments

The UK has a good story to tell on the development of guidance on how an economic appraisal framework should be applied in developing environmental policies, and in ensuring that environmental costs and benefits are fully incorporated into other policy development. The KPMG study confirmed that the Policy Appraisal and the Environment guidance had been used throughout Whitehall, but had not been applied uniformly.

The experience to date in a number of areas of application, as alluded to above, should provide encouragement for policy makers keen to apply a similarly economically-coherent framework to the risk management of chemicals. As the case study on short chain chlorinated paraffins (SCCPs) carried out by consultants RPA has shown, semi-quantification of costs and benefits can provide an important contribution to policy making; the inability to fully monetise all the relevant costs and benefits should not deter further applications of the risk-benefit analysis framework - it represents an important tool-kit and aid to decision making.

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CHAIRMAN'S REPORT:

**OECD WORKSHOP ON THE INTEGRATION OF SOCIO-
ECONOMIC ANALYSIS IN CHEMICAL RISK
MANAGEMENT DECISION MAKING**

Workshop Chairs:

Professor Peter Calow, University of Sheffield (UK)

Gary Nash, Director General, International Council on Metals and the Environment

Breakout Session Co-Chairs:

Session A -- Mary Ellen Weber (US EPA)
Guy Thiran (BIAC/ICME)

Session B -- Joe Carra (US EPA)
Elizabeth Surkovic (BIAC/UK CIA)

Session C -- John Keating (Department of Natural Resources, Canada)
Elin Eysenbach (BIAC/Procter and Gamble, US)

Workshop Rapporteurs:

John Atherton (BIAC/NiDI)

Jim Solyst (BIAC/US Chemical Manufacturers Association)

Robin Hill (Department of Health, Canada)

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INTRODUCTION

Organisation of Workshop

The OECD Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making was organised by the United Kingdom and BIAC (the Business and Industry Advisory Committee to the OECD), in co-operation with Canada, Japan, the United States, the European Commission and TUAC (the Trade Union Advisory Committee to the OECD). Financial resources to fund the Workshop were provided by the following:

- the UK Government
- Association of Swedish Chemicals Industries
- Association of the Dutch Chemical Industry (VNCI)
- Canadian Chemical Producers Association (CCPA)
- European Chemical Industry Council (CEFIC)
- European Chlorine Manufacturers Association (Euro Chlor)
- Federation of Norwegian Process Industries (PIL)
- International Council on Metals and the Environment (ICME)
- Japan Chemical Industry Association (JCIA)
- Nickel Development Institute (NiDI)
- US Chemical Manufacturers Association (CMA)
- US Council of International Business (USCIB)
- Verband der Chemischen Industrie e.V. (VCI) (Germany)

Workshop Objectives

The Workshop was designed to bring together analysts and risk managers to further the integration of socio-economic analysis in chemical risk management decision making by:

- providing basic information on the general techniques, approaches and terminology used in the development and application of socio-economic analysis (i.e. describing what exists and how it is used);
- sharing experiences and identifying expertise; identifying effective techniques and approaches; highlighting any problems encountered and considering solutions. This would include discussions on: when such an analysis might be appropriate (e.g. in a national, regional or international context); where barriers to its wider use exist and how they may be overcome; and what approaches have been used for valuing costs and benefits;
- identifying areas that need further work within the OECD and Member countries and the means for carrying such work forward.

Format of the Workshop

The Workshop comprised six sections held in sequence, each one adding a layer of information necessary for achieving the Workshop objectives. These sections included:

- 1) two *keynote addresses* which set the stage for the discussions that followed;
- 2) a “*background/educational session*”, which provided participants with the opportunity to learn about basic techniques, terminology and approaches used in socio-economic analysis;
- 3) a session devoted to the *presentation of issue papers or case studies*, which highlighted the experiences (both good and bad) of government and industry representatives with respect to the development and use of socio-economic analysis;
- 4) a *panel discussion* by people who work, or have worked, at the interface between socio-economic analysts and risk management policy experts;
- 5) three *breakout sessions* held in parallel, which in consideration of the information provided in sections 1 through 4 and other information: 1) identified problems with current approaches for developing and using socio-economic analysis; 2) identified those facets that are particularly effective and should be continued; and 3) made recommendations;
- 6) a *concluding session*, in which the results of the breakout sessions were discussed and the final Workshop Report was developed. **(The final report is not part of this Chairman’s Report, but is a separate document.)**

SUMMARY OF WORKSHOP DISCUSSIONS

The following is a summary of the general discussions and main points raised during the Workshop. *No attempt has been made to summarise the formal presentations made during the Workshop*, as the full text of these presentations has already been included in background material provided to Workshop participants and, most likely, will also be included in Workshop proceedings to be published by OECD.

Plenary Session (7 January)

The co-chairs for the Workshop, Professor Peter Calow and Mr. Gary Nash, opened the Workshop and welcomed participants to London. The co-chairs discussed the organisation of the Workshop and how its objectives fit within the context of the activities under OECD's Risk Management Programme. Finally, the co-chairs described how the results of the Workshop (particularly the conclusions and recommendations) would be considered by OECD's Advisory Group on Risk Management in early February in order to determine a future course of action.

Dr. John Graham (Harvard University School of Public Health; Center for Risk Analysis) and Professor David Pearce (University College London) provided keynote addresses. Following this, a background session was held to introduce the following concepts to the Workshop (the presenters for each item are included in parentheses): *Fundamentals of Risk Assessment* (Henri de Henau, Procter and Gamble); *Development of Risk Management Options* (Meg Postle, Risk & Policy Analysts Ltd.); *Methodology for Developing Socio-Economic Analysis* (Meg Postle) and *Risk Management Decision Making* (Meg Postle).

The remainder of the Plenary Session, described below, was devoted to a series of presentations of case studies. The following summarises the Workshop discussions of these case studies.

Methodologies for Developing Socio-Economic Analysis

Session A

There was agreement that socio-economic analysis (SEA) is an essential element of risk management decision making and that it should be integrated into *every* stage of the risk management process. (This message was also adopted later during the Plenary Session.) However, it was recognised that prioritising and using wisely the limited resources in the analysis process is critical. It is also important to understand that SEA should be conducted in a hierarchical manner, with the level of analysis being appropriate to the severity of the problem.

There was some discussion regarding the utility of quantitative, qualitative and semi-qualitative assessments. Some participants put a high value on quantitative assessment and believed that a significant effort should be made to assign monetary as well as numerical values to elements in the assessment. Others believed that quantitative or even qualitative assessments were adequate in certain situations.

There was agreement that stakeholder involvement in the SEA process is essential. The regulated community needs to be consulted often and early in the SEA process (for example, regarding the accuracy of information used to estimate the costs and benefits of various options), as this will enhance policy implementation. Other stakeholders, such as consumers, may also need to be consulted regarding

the design, desirability and appropriateness of risk management options. Some of these stakeholders may need financial assistance in order to participate. There was also agreement that risk assessors and economists need to work together, preferably during all phases of SEA. To facilitate this, some attempt should be made to develop and use common terminology.

Session B

This discussion highlighted a number of important factors relevant to successful implementation of socio-economic analysis in risk management decision making. It was noted that an interdisciplinary approach based around a common framework of methodology was vital. There was a common appreciation of the difficulty in involving certain stakeholders, either because their relevance was difficult to determine or because they lacked the resources with which to take part. The lack of involvement of consumer groups in this process was highlighted. The paucity of data necessary to conduct a socio-economic analysis (e.g. benefits data) and the lack of effective criteria for conducting such analysis was a common concern to many, leading to calls for work on the valuation of environmental damages and benefits.

Integration of Socio-Economic Analysis in Risk Management Decision Making

Session C

The Workshop discussed the need for conducting some form of retrospective analysis, to examine whether original estimates of costs and benefits were correct and to provide an audit of benefits arising from an earlier risk management decision. However, the Workshop noted that the results of retrospective evaluations could be misleading if the data used for the evaluation were not available at the time the original risk management decision was taken.

The issue of the involvement of all stakeholders was raised again, with some participants questioning whether the opinions of any one stakeholder were more important or valid than the opinions of other stakeholders. Other participants believed that it was most important to involve only those who may be directly affected by a risk management decision. It was clear, however, that the early involvement of stakeholders will help to ensure that any assumptions made in the analysis are appropriate and that the conclusions are comprehensive and constructive.

A question was raised as to whether indirect benefits (those acquired beyond the intended benefits of a risk management decision) should be accounted for in a cost-benefit analysis. Participants who believed that all benefits (direct and indirect) should be included within the analysis were challenged to consider whether this meant that indirect costs (i.e. impacts on downstream businesses) should also be identified.

Plenary Session (8 January)

Working at the Interface Between Socio-Economic Analysts and Risk Management Policy Managers

The session opened with individual presentations from a panel of four experts, who shared with the Workshop their experiences with socio-economic analysis from the standpoint of either an economist or a risk manager.

Addressing the interdisciplinary context of socio-economic analysis, the Workshop participants identified the need to develop a framework for action. A forum involving all stakeholders was (or should be) the most typical approach for ensuring that relevant factors are considered.

Developing further the issue of stakeholder involvement, there was a general acknowledgement of the need to understand the differing perceptions of stakeholders, notably how information on risks and costs and benefits is received as well as communicated, in order to optimise their involvement in and appreciation of the decision making process. The importance of involving consumers was reiterated, with one participant claiming that about three quarters of general public exposure to chemicals is via consumer goods.

Several participants expressed a concern that implementation of policy framed by cost-benefit analysis might go beyond identifying preferable levels of protection but also how to achieve these levels which may impose inappropriate constraints on industry's ability to operate efficiently and stifle innovation. A proposal was advanced that risk managers should consider setting goals and leave industry to determine how best to arrive at them, since cost efficiency is a key driver of most industrial operations.

Involvement of economists early in the development and selection of risk management options, and the maintenance of contact throughout, were seen as paramount. There was some concern that economic issues were sometimes considered too late in the process; however, there was also the recognition that economics should be considered only as one input to the risk management debate and would not necessarily be the dominant consideration driving the final decision.

Data gathering and data quality were considered as paramount in the development of a successful analysis. Equally important, results should be presented in a coherent and transparent manner which is accessible to economists and non-economists alike.

The view that socio-economic analysis should be seen as a tool for incorporating a consideration of environmental impacts in all government policy decisions was supported by many participants. Methodologies for performing qualitative, semi-quantitative, fully quantitative and monetized cost-benefit analyses should all be readily available and risk managers should have the flexibility to adopt any of these with sufficient justification.

Breakout Sessions (8 January)

Following the panel discussion, Workshop participants were divided into three breakout sessions, each meeting in parallel. The purpose of each session was to develop a report which identified problems with the way socio-economic analysis is currently conducted and the results used, but which also identified those facets that are particularly effective. This included discussion on when such an analysis might be appropriate (e.g. in a national, regional or international context); where barriers to its wider use exist and how they may be overcome; and what areas need further work within the OECD and Member countries and the means for carrying such work forward.

Once these breakout sessions concluded their discussions and prepared their reports, the Workshop participants re-convened in plenary. A co-chair or rapporteur from each session presented the conclusions and recommendations developed in their session.

[The reports of each Breakout Session can be found in Annexes 1-3.]

During the evening, the Workshop and breakout session co-chairs and rapporteurs reviewed each breakout session report and developed a consolidated report which captured the key points raised in each session.

Plenary Session (9 January)

Discussion of Consolidated Paper (Final Workshop Report)

A copy of the consolidated paper/Workshop Report was distributed to Workshop participants prior to the beginning of the Plenary Session.

The session was opened by co-chair Professor Calow, who sketched out the future path of the Workshop Report: following a discussion of the draft in the Plenary Session, the document would be appropriately modified to reflect the points raised. This final document would be presented to the Advisory Group on Risk Management meeting in Paris on 9-10 February. Professor Calow noted that the Report to the Advisory Group should be short. Furthermore, it should be borne in mind when making any recommendations that many of those participating in the Workshop were not experts in socio-economic analysis (SEA). Professor Calow then sketched out the main features of the report, following which he went through it section by section asking for comments and inviting suggestions for changes in wording. These comments were duly noted. The final Workshop Report, along with the Chairman's Report, would be distributed to Workshop participants in early February.

Chairman's Summary of Workshop Discussions

Professor Calow provided a recapitulation of the major themes and concepts raised during the Workshop and provided his conclusions on these discussions:

The implementation of environmental protection measures almost by definition leads to restrictions on some aspect of human activity and the emanations from it. So whether they derive from the precautionary principle, hazard identification or risk assessment, these measures inevitably involve the need to balance gains for human health and ecological systems against lost benefits arising from the controlled activity for human health and welfare, employment and other aspects of the economy. Chemicals, the subject of the Workshop, are produced because they bring benefits in terms of human health and welfare, and play an important part in the employment and economy of many countries, yet they have the potential to cause harm to human health and non-target species and ecosystems.

The problem is that balancing judgements about the relative advantages and drawbacks of chemicals, ultimately made by regulators and politicians, is often subjective and sometimes obscure. One major aim, therefore, of the integration of socio-economic analysis in chemical risk management decision making is to make explicit what is usually implicit, in a way that is open to scrutiny, discussion and challenge. The details of particular cases might be subject to disagreement in terms of how much importance is associated with this or that element, but it ought to be possible to develop a common framework of principles and language that is mutually acceptable across the different professional communities and states interacting around common problems of environmental protection.

A number of related benefits should arise out of the adoption of common principles in the application of socio-economic analysis to risk management:

- 1) The rationale behind decisions should become more transparent.
- 2) Benefits can be maximised for a given level of costs, or costs can be minimized for a given level of benefits (both of which involve cost-effectiveness analysis) or net benefits (benefits minus costs) can be maximised. Regardless of which type of analysis is performed, transparency of methods and assumptions is crucial.
- 3) At the same time, it should be possible to identify who enjoys benefits and who suffers costs, so that best or at least most acceptable solutions can be identified.
- 4) If it is assumed that the resources available for environmental protection are limited, then optimising them by using a transparent cost-benefit analysis while taking into consideration distributional effects will be consistent with promoting sustainable development.
- 5) It is often argued that risk assessments should be protected from “contamination” by risk management. The former ought to be based on unbiased science, whereas the latter is inevitably influenced by social and political considerations. However, risk assessors need to know what kind of information managers need (and in what units of measurement and time frames). The integration of risk assessment and socio-economic analysis is an iterative process and must be co-ordinated between all the analysts. Bringing together socio-economists with risk assessors ought to provide better guidance for making risk assessment more useful.
- 6) Last, but certainly not least, making the process of management decision making more transparent provides a better basis for stakeholder understanding and involvement. Since both risk assessment and socio-economic analyses are very technical and can be complex, a major challenge will be to present the information in an easily understandable and usable form. It will be especially helpful to build greater relevance and usefulness into these analyses based on opportunities that arise from more openness, to enable more effective involvement of the public as consumers and as concerned citizens.

The Workshop focused attention on the risks arising from commercial chemicals and their management, but it ought to be possible to generalise the lessons for at least two reasons. First, chemicals are at the heart of most environmental problems. Second, socio-economic analysis is based on fundamental principles of resource use and social equity that ought to apply in a way that is not subject to particular circumstances.

It is for all these reasons that socio-economic analysis is increasingly being applied to environmental protection by governments across much of the developed world. Given the globalization of marketplaces, especially involving chemicals, and the international dimension of most environmental problems, there is an obvious need for international co-operation in environmental risk management. It follows that there is much to be said for seeking common language and common principles in socio-economic analyses that are mutually acceptable and that can be easily and effectively promulgated in developing states. OECD clearly has an important part to play in the process, and the output of this Workshop made a number of recommendations on how this might be achieved.

Reflections from Keynote Speakers and Co-Chairs

John Graham -- In his concluding remarks, Dr. Graham noted that a lot of ground had been covered in the past two days. He then went on to pose three questions. **Firstly:** Do governments, NGOs and other groups in society who influence decision making have the resources to participate in, and expertise in the field of, developing SEA? Most stakeholder groups, including industry, seem to have a rather limited expertise in SEA, and need to become better equipped for the future. **Secondly:** Dr. Graham saw a need to incorporate the precautionary principle into the regulatory framework based on SEA. The precautionary principle in itself is not very helpful, because it provides no basis for a sensible balance between uncertain risks, costs and benefits. More recently, however, more sophisticated versions of precautionary thinking have been developed, which are operationalised in various “value of information” (VOI) tools. In effect, VOI treats further study as a formal risk management option, and examines the costs and benefits of proceeding in terms of reductions in risk and costs that are likely to result from better informed decisions. The VOI method has already been applied to diverse problems and the results thereof published in the literature, and there may be a role for OECD in exploring the role of such methodologies in the context of chemical regulation.

The final question posed by Dr. Graham concerned the range of political or regulatory discretion that is appropriate when making decisions. Some may hold that cost-benefit considerations should drive decision making, while at the other extreme there are those who believe that risk, cost and benefit information should only play a minor role. Whatever approach is taken, it is important that the decision maker clearly explain to the public what particular decision was made and why, for example, the final decision was or was not driven by an economic analysis or other considerations.

David Pearce -- In his concluding remarks, Professor Pearce presented a conceptual framework for analysing chemical risks. He pointed out that the focus of economic analysis was different for new chemicals as compared to existing chemicals. For example, for new chemicals the benefits are expressed in terms of avoided damage, whereas for existing chemicals the benefits that arise are associated with those of risk reduction. Similarly, the costs for new chemicals are associated with foregone benefits, whereas those for existing chemicals are associated with the costs of reducing risks.

After discussing how these various costs and benefits can be estimated, Professor Pearce gave a personal vision of the precautionary principle, and ended his presentation with a series of recommendations for further possible action by OECD. He suggested that OECD should:

- develop a handbook on risk appraisal, including risk-risk, cost-benefit, cost effectiveness and multi-criteria approaches;
- make an inventory of monetary valuation studies of chemical risks. This study could initially be based on contributions from the US, Canada and the UK, etc. and could be followed up by a workshop;
- hold a training workshop for risk appraisers;
- conduct a retrospective policy analysis which considered, for example, a) the implicit value of a statistical life (e.g. from asbestos in the US); b) the costs of risk regulation; and c) the benefits of risk regulation.

Peter Calow had two closing comments to make, one from a professional standpoint and the other as an amateur. From the professional standpoint he recognised the inadequacies of defining “harm” to an ecosystem. As a result, it is still difficult to describe the economy of nature and evaluate ecosystems in an adequate manner. From an amateur perspective, one of the features of the week’s activities had been

a realisation of the importance of risk communication in the management of risks, and in particular the necessity for communication to be a two-way process.

Gary Nash noted that concern about the environment was still at a high level. This concern was unlikely to change in the future, as both government and industry must inevitably continue to manage environmental risks. However, the resources available for this activity are limited, and therefore a sound economic analysis is of importance to both the private and the public sectors.

The credibility of the various groups within society was also an issue that must be faced, with various constituencies having different credibility in the public's eye. Of vital importance for improving credibility, besides maintaining openness and transparency, is that individual constituencies provide sound analyses of the risks encountered.

ANNEXES

ANNEX 1: REPORT FROM BREAKOUT SESSION A

Co-Chairs: Mary Ellen Weber (US EPA)
Guy Thiran (BIAC/ICME)

Rapporteur: John Atherton (BIAC/NiDI)

The participants in Breakout Session A discussed a number of key issues at length and concluded by agreeing that the OECD should adopt a policy stating that: **“Socio-economic analysis should be an inherent component of all aspects of chemical risk management decision making.”**

The OECD should assist Member countries in implementing this policy by:

1) surveying current practices in Member countries and compiling illustrative examples (logistics, peer review)

The group recognised that the term socio-economic analysis covered a wide range of techniques. A survey of these techniques would enable a fuller appreciation of the extent to which socio-economic analysis was being used by Member countries and the context in which it was applied. The survey could provide a synthesis of available information, including the sources that are available and how to access these sources. Particular elements of socio-economic analysis which the group felt should be explored in some detail were logistics and mechanisms for peer review. The commonality between cost-benefit analysis and life-cycle analysis was noted and the group considered that discussion between the practitioners of these two disciplines may prove to be of mutual benefit.

2) conducting an empirical study of the circumstances under which socio-economic analysis influenced, or did not influence, policy decisions

The group agreed that this study should examine the factors which were particularly influential in the final risk management decisions and identify the degree to which the process was transparent. The levels of uncertainty should be explained and any value judgments noted.

On the basis of the results of both the survey and studies, data gaps and research needs should be identified.

3) reviewing a selected set of completed socio-economic studies to assess their accuracy

Otherwise known as “retrospective analysis”, this review should seek to verify the accuracy of socio-economic analysis, highlight sensitive components, and identify mechanisms for integrating the results of retrospective analysis in risk management policy review.

4) holding a joint meeting between economists and risk assessors to enhance communications

Chemical risk assessments, while useful for many purposes, often do not provide the information that is necessary to develop a socio-economic analysis. For example, risk assessments often address only the most sensitive endpoint, but economists need information on all important endpoints in order to conduct a benefits analysis. As another example, risk assessments often report only risk to a single, hypothetical individual rather than reporting the risk to the population as a whole which is used in economic analyses. A joint meeting between economists and risk assessors could identify the information needed by economists and the ability of risk assessors to provide that information.

5) OECD should serve as an information clearing house for the exchange of:

- methodologies used by countries/industry
- databases containing, among other things, values for relevant environmental/health benefits
- studies already conducted.

In particular, the group acknowledged that estimating money benefits for risk reduction can be expensive and time consuming. The ability to transfer benefits information from one context to another could help make socio-economic analysis more efficient and transparent. The group recommended that this exercise include the transfer of information between the OECD and non-Member countries.

6) OECD should develop models of ways private funding of data generation could be used while still ensuring that the data are viewed as credible.

The discussion highlighted a common dilemma, namely that regulators lack resources to fund research and that stakeholder-funded research may be rejected as lacking credibility. A survey of approaches used in Member countries to resolve this paradox could elucidate common elements of an OECD model.

7) The ultimate product of the OECD work in this field should be a guidance document for Member countries which engage in socio-economic analysis.

The group felt that such guidance should include: a listing of the range of techniques available and when it is appropriate to use these techniques; a discussion of how to involve stakeholders and ensure that the process is transparent; a list of relevant sources of information and how to access these sources; and mechanisms for peer review.

ANNEX 2: REPORT FROM BREAKOUT SESSION B

Co-Chairs: Joe Carra (US EPA)
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Rapporteur: Robin Hill (Department of Health, Canada)

GENERAL CONCLUSIONS

Goals

- Socio-economic analysis (SEA) for chemical risk management decision making comprises a range of tools and can be complementary to other approaches;
- There appears to be a general consensus that SEA should be used in decision making. However, in its application the following should be taken into consideration:
 - ◇ Socio-economic analysis should be used in its widest sense;
 - ◇ There should be openness to full NGO participation;
 - ◇ There should be a flexible framework which is not method-driven but problem-driven;
 - ◇ Qualitative assessments should be accepted in some cases where quantification is not feasible. For example, when benefits cannot be quantified, let alone monetized, it is important to fully examine and weight qualitative presentations of benefits;
 - ◇ There should be guidelines on what form of analysis is appropriate under given circumstances;
 - ◇ The depth of analysis should be decided on a case-by-case basis;
 - ◇ To the extent possible, and resources permitting, all the costs and benefits used in the analysis (whether quantifiable or not) should be identified as completely as possible;
 - ◇ Quantified benefits should not necessarily be valued over unquantified benefits.

RECOMMENDATIONS FOR OECD

OECD should:

- develop and further promote SEA, and take a leading role in promoting SEA globally in international chemical risk management;
- frame the generic principles and develop a framework to move SEA forward, taking into consideration a number of factors;

- describe SEA in a wide-ranging sense as including a variety of approaches and concepts such as, but not restricted to: cost-benefit analysis, cost-effectiveness analysis, decision analysis and multi-criteria analysis;
- promote a common understanding of socio-economic analysis, and acknowledge that it is one element which can inform decision making and, in that way, complement the precautionary principle (as defined by UNCED);
- develop an approach for the involvement of all stakeholders, to ensure that the whole process (both the design of risk management options and the assessment of the costs and benefits of these options) is made transparent. In particular, OECD should develop an approach for the more active participation of consumer groups, NGOs and other stakeholders which do not normally participate in the option selection/decision making process;
- collect and assess examples of SEA use in chemical risk management decision making, examining both positive and negative experiences and drawing some generic conclusions on the applicability (i.e. were they used and how?) and effectiveness of SEA tools on a case-by-case basis. OECD could consider whether a workshop could be convened to further discuss these issues in the widest sense;
- explore areas which are not well developed (e.g. the valuation of environmental effects) and propose how these could be better developed. There appears to be a need for more work on socio-economic valuation of the environment's contribution to human well-being (e.g. ecological services, health, etc.);
- consider how to develop SEA-relevant databases for sharing among Member countries;
- promote, through good communication, an understanding of the implications of various risk management options based on socio-economic analysis.

ANNEX 3: REPORT FROM BREAKOUT SESSION C

- Co-Chairs:** John Keating (Department of Natural Resources, Canada)
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- Rapporteur:** Jim Solyst (US Chemical Manufacturers Association)

To help focus discussions and identify contributing factors or impediments to the use of socio-economic analyses, the following two broad topics were used: "Methodologies for Developing Socio-Economic Analysis" and "Integration of Socio-economic Analysis in Chemical Risk Management Decision Making". During discussions the group acknowledged the need to consider social, economic and environmental requirements if society is to achieve sustainable development (SD). The use of socio-economic analysis in chemical risk management decision making was seen as one tool to support the goal of SD. Appendix 1 lists effective and problematic factors relating to each of the two topics, along with some resulting ideas for additional consideration that were catalogued by the group.

Building from these initial discussions, the group identified the following critical factors that should be considered when attempting to achieve the overall goal of the Workshop. It should be recognised that these are not the only important factors, but are those factors that individuals in the group felt should be considered first. The group then developed a series of recommendations in response to these factors.

CRITICAL FACTORS

- how to allow for early stakeholder involvement; how to ensure that the regulated community is actively involved and will be supportive during the implementation phase; the need to be prepared to provide assistance to consumer and other public-based groups to ensure their participation;
- the need to identify certain basic principles:
 - ◊ use of a tiered approach, with the level of analysis being commensurate with the severity of the problem addressed;
 - ◊ identification of a baseline of data required to conduct a useful SEA;
 - ◊ characterisation of the quality of the data used in the SEA;
 - ◊ agreement on the definition of key terms;
 - ◊ use of a process that is transparent to stakeholders and the general public;
- the need to prescribe a process for assigning assumptions, social values and degree of uncertainty;
- how to ensure that the decision and process can be communicated to key audiences, including stakeholders, the media and the general public;
- the importance of conducting periodic post-hoc evaluations of the SEA process.

RECOMMENDATIONS

- 1) OECD Member countries should share SEA experiences, approaches and methodologies. The OECD should develop guidance regarding the type and format of information Member countries should provide. The OECD should survey Member countries, categorise the information it receives, and make it readily available. Of particular use would be the following types of information: the added value SEA brings to the decision making process; case studies; retrospective/post-hoc analyses; lists of contact and resource people.
- 2) OECD should use the information provided by Member countries to develop an SEA framework that could be used by Member countries and others as they conduct specific analyses or in the development of SEA policy. The framework would focus on the following factors:
 - ◇ stakeholder involvement;
 - ◇ hierarchical, step-wise approach;
 - ◇ definition of terms;
 - ◇ baseline data;
 - ◇ transparency;
 - ◇ interpretation of results;
 - ◇ social and economic values;
 - ◇ peer review;
 - ◇ assumptions;
 - ◇ uncertainty.
- 3) Economists and risk assessors need to work closely together. They need to agree on a common terminology and understanding of the principles and goals of both disciplines. Guidance for conducting risk assessments should include a reference to the need for providing relevant information to support SEA. Economists should be represented on the OECD's Advisory Group on Risk Management.

Appendix 1 to Breakout Group C Report

I. Methodologies

The group discussed the aspects of socio-economic analysis (SEA) methodology which have been necessary and effective and those which have been problematic and required improvement. Resulting ideas have also been noted, but do not necessarily reflect consensus. They are offered to assist further thinking along these lines.

Effective (factors shown to enhance success):

- having an agreed method or framework that is generic and principle based, and that contains the basic elements or general parameters needed. The framework should not be too prescriptive;
- setting clear goals;
- developing a benefits database (e.g. as done in Canada) which can serve as a model or basis for data collection;
- establishing criteria for conducting SEA;
- defining what data are needed to allow quality decision making to proceed;
- defining key terms and ensuring that the analysis is written in a way that will allow for understanding by people with different expertise. This can occur if the key players are involved in a continuous dialogue;
- defining when economists should be involved in the chemical risk management process.

Problematic (factors which, when resolved or addressed, would enhance success):

- lack of transparency during various stages of the risk management process (e.g. decision making);
- lack of adequate data for qualitative and semi-quantitative analyses. Even when a step-wise approach is used, each level still needs relevant data;
- lack of data needed to conduct evaluations of substitutes;
- data confidentiality;
- difficulty of developing a comprehensive evaluation (need to incorporate judgements; “boxes” are not enough; balance among the many factors is needed);
- difficulty of determining appropriate valuations, e.g. value of statistical life, default industry activities;
- without adequate data, need to rely on default values;
- broad risk reduction measures affecting applicability of default values;
- difficulty of having consistent core assumptions in an international context (it may be worthwhile to survey at what level countries value a “statistical life” and attempt to understand why these values differ);

- recommendations from risk assessments not being as helpful as they could be (e.g. risk characterisation should present uncertainty and probability better);
- small and medium enterprise (SME) concerns may differ from those of large global companies;
- and it is more difficult for SMEs to participate in the process;
- differences in discounting approaches (as well as in when and whether to discount values);
- the need to address uncertainties.

Resulting ideas:

- Categorisation of information presented during the Workshop (e.g. what worked, what didn't and why) could be of value as a first step;
- Develop an agreed method, such as a flexible framework, for making SEA more prevalent in chemical risk decision making. It should be principle-based, containing the basic elements or general parameters. Something general will be more useful than something too prescriptive;
- Develop new tools (or modify existing ones) to take into account the concept of sustainable development. On-going work in this area, such as the sustainable development "tool kit", should be investigated to avoid duplication;
- Develop examples and case studies and communicate them to relevant parties;
- Take the "precautionary principle" into account;
- When developing guidance, conduct the process in a step-wise manner. First, identify criteria for use of SEA and include things like:
 - ◊ setting objectives;
 - ◊ understanding boundaries or limitations;
 - ◊ data availability concerns;
 - ◊ efficiency in prioritising resources, and the concept that the level of detail for the SEA should depend on the nature of the outcome or decision; later, explore processes through flow-sheet development, addressing valuation issues, and providing opportunity for consensus dialogue.
- Examine the feasibility of conducting an exercise (similar to that underway under the Advisory Body for exchanging risk assessments) which would facilitate the exchange of completed SEA across OECD countries. OECD has a process for developing guidance for data collection, risk assessment and risk characterisation that could serve as a model for future consensus dialogue and guidance development in the area of socio-economic analysis.

II. Integration

Based on the discussions above concerning methodologies, the group identified elements of the integration process for socio-economic analysis which have been effective and those which have been problematic in chemical risk management. A few resulting ideas have also been noted. They do not necessarily reflect consensus, but are offered only to assist further thinking along these lines.

Effective (factors shown to enhance success):

- Peer review of SEA, similar to that for risk assessments, has been effective in assuring a quality analysis and its acceptance on completion. The group shared experiences of SEA undergoing peer review during and after its development via steering, stakeholder and advisory groups. Confidence in outcome is enhanced by peer, public and stakeholder review;
- Industry can provide a valuable resource (e.g. data) to support risk assessments and socio-economic analyses for government decision making. Steps may be needed to assure that industry contributions are accepted by all stakeholders;
- Another factor is government recognition of the burden placed on SMEs and provision of assistance (e.g. US EPA/Design for the Environment);
- Iterative and interactive approaches to conducting analyses that involve decision makers, assessors and others help ensure that the resources expended are commensurate with the level of decision required. This may include an initial SEA at an early stage to help define data and other requirements, followed as needed by more detailed analyses.

Problematic (factors which, when improved or addressed, would enhance success):

- poor linkages and information flow between economists and risk policy or risk management people;
- late involvement of economists in risk assessment and risk management activities, not just in a segmented socio-economic analysis (need to consider cost and priority relative to decision outcome);
- lack of involvement of risk assessors in SEA deliberations, default selections, etc.;
- too little, or late, involvement of decision makers in the process of developing SEA, e.g. greater European Community involvement in Member country risk and socio-economic assessments;
- difficulty of determining at what level SEA should be done;
- lack of “business impact” software;
- insufficient resources to conduct a proper evaluation (typical to ask staff to do “more with less” in terms of resources); too few economists available to fully address the needs; improving integration will likely place further demands on personnel;
- existing legislative structures (e.g. US or regional practices) limiting flexibility in regard to choosing a consultative process;
- sometimes substantial gaps in understanding among government professionals and political appointees; political appointees may make decisions based on policy, large financial impact or high public profile; political appointees and politicians may override findings and recommendations of government professionals;
- ignoring SEA, or politicisation of the results, acts as a disincentive for future involvement of industry and other stakeholders in the process;
- too much reliance on uncertainties, assumptions and unknown values increasing the difficulty of obtaining professional, public and stakeholder acceptance of SEA results or recommendations;

- with respect to evaluating the risks and benefits of potential substitutes, including chemicals or chemical processes, concern that faulty decisions may be made due to significant data gaps and special difficulties when information concerning new or innovative techniques is confidential;
- use of confidentiality being a possible barrier to SEA, although it can usually be negotiated;
- assumptions used often being hidden in the software, which highlights the importance of defining procedures to increase trust;
- failure to agree on the process presenting a barrier to improving trust in the SEA results;
- lack of clarity concerning when SEA can be a driving force, e.g. through establishing benchmarks for decisions.

Resulting ideas:

- Could SEA tools be developed and broadly accepted through OECD dialogue, similar to on-going risk assessment work?
- Would principles for a common approach to data development help improve industry accountability and public trust, similarly to how the use of OECD's Principles of Good Laboratory Practice has worked for test data?

**FINAL REPORT ON THE CONCLUSIONS AND
RECOMMENDATIONS FROM THE WORKSHOP**

Final Report on the Conclusions and Recommendations from the Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making

Conclusions

The workshop agreed that socio-economic analysis should be a component, both in the early and later stages of risk management decision-making for chemicals, and that OECD should take a leading role in developing, promoting, and assisting in implementing it on a global scale.

Recommendations

In order to achieve the above objective, the workshop made the following recommendations:

Recommendation 1

OECD should develop a flexible framework for integrating socio-economic analysis into chemical risk management, which should include but not be limited to the following:

- a rationale for the involvement of all stakeholders which ensures that the process as well as the outcomes of analyses are transparent
- a basis for examination of the range of possible risk management measures
- a range of available tools including cost-effectiveness analysis, cost-benefit analysis, multi-criteria analysis etc.
- an approach which involves the use of qualitative, semi-quantitative and fully quantitative analysis at the level of sophistication appropriate to the decision being made
- an identification of basic data requirements and the addressing of issues covering data quality and availability
- to the extent possible, and resources permitting, an examination of all the costs, benefits and distributional impacts (socio-economic, spatial, and temporal) considered within the analysis
- an examination of methodological issues such as discounting, valuation of human health and environmental effects, and “benefit transfer”
- a recognition of the need to consider the implications of substitutes, their availability, efficacy, cost, and associated risks
- a promotion of the use of uncertainty analysis on key assumptions
- guidance on the interpretation of results
- a recognition that full consideration be given to all quantified and non-quantified impacts, and

- a requirement that the results be presented in a clear, concise and transparent manner, stating all assumptions, associated uncertainties and probabilities.

Recommendation 2

OECD should facilitate the implementation of socio-economic analyses by establishing a mechanism for sharing information regarding current practices among Member countries. This should result in easy access to a comprehensive set of databases, methodologies and experiences.

The methodologies would encompass a full range of approaches for both qualitative and quantitative analyses in the context in which they are practised. For example, these might include screening and ranking techniques, market-based valuation approaches and experimental market approaches (e.g. contingent valuation).

The OECD may want to consider a range of mechanisms for achieving the above, for example, surveys or requests for information. Consideration should also be given to how this will be maintained as a readily accessible and regularly updated information clearing house.

Recommendation 3

OECD Member countries should undertake retrospective studies to help Member and non-member countries determine under what circumstances socio-economic analysis influenced chemical risk management decisions. This should help identify when such analyses could provide added value to decision making. In addition, this review should determine under what circumstances there tends to be either an underestimation or an overestimation of costs and benefits. The OECD should act as a clearing house to compile, analyse and disseminate the results of these analyses to Member countries.

Recommendation 4

In order to ensure that adequate and appropriate data and parameters are available for undertaking socio-economic analysis, the OECD Secretariat should explore the interest of the Risk Assessment Advisory Body and the Group on Economic and Environmental Policy Integration in establishing a mechanism for communication between risk assessors and economists.

The intention of this mechanism is to ensure that risk assessors provide the type of data required for a complete and robust socio-economic analysis, including:

- use of common language
- characterisation of the full range of effects on human health and the environment
- derivation of probabilistic rather than point estimates.

It should be noted that in order to accomplish this aim, it is necessary that this be a two-way process between the risk assessors and the economists.

Recommendation 5

OECD should, building on workable models in Member countries, develop a protocol for ensuring that within the context of socio-economic analysis, data gathered through private means is as credible as that gathered through public means.

The workshop acknowledged that it may be necessary to form an ad hoc working group to carry out these recommendations.

Risk communication and risk perceptions are important considerations in the development and application of socio-economic analysis and deserve appropriate attention. However, the workshop recognised that a parallel activity within the Risk Management Programme is considering this issue in a broader context and will make recommendations to the Advisory Group.

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