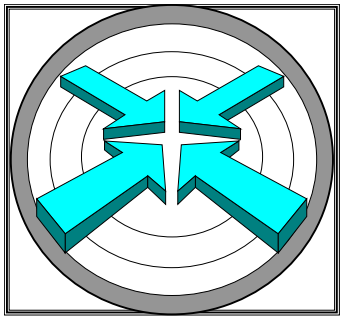
PROCEEDINGS

of the



WORKSHOP

on the

CONVERGENCE OF RISK ASSESSMENT AND SOCIO-ECONOMIC ANALYSIS TO BETTER INFORM CHEMICAL RISK MANAGEMENT DECISIONS

May 1-2, 2000
Arlington, VA

Workshop Sponsors:

United States Environmental Protection Agency
The Government of Canada
The American Chemistry Council
(previously The Chemical Manufacturers Association)
The International Council on Metals and the Environment
The Society for Risk Analysis
Resources for the Future
The Procter & Gamble Company
Organized in co-operation with the Organization for Economic Co-operation and Development

FOREWORD

These Proceedings contain the Co-Chairs' Report and the Principles and Recommendations generated by the participants in the Workshop on the Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions, held in Arlington, VA, USA on 1-2 May 2000. Also included are the Workshop presentations[1], a summary of ideas discussed in breakout sessions, and other relevant information.

This Workshop topic seeks to fulfill and expand upon recommendations from two previous initiatives:

- The Organization for Economic Co-operation and Development (OECD) Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision-Making, London, January 1998. (See http://www.oecd.org/ehs/rskreprt.htm)
- The (USA) Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making, 1997. (See http://www.oecd.org/ehs/rskreprt.htm)

[1] Presentation materials have been provided by the presenters or noted from their remarks and do not represent opinions or policies of their organization of affiliation or of any other organization.

ACKNOWLEDGMENTS

The Workshop Planning Committee wishes to acknowledge all participants in the Workshop on the Convergence of Risk Assessment and Economic Analysis to Better Inform Chemical Risk Management Decisions for their contributions of expertise and ideas, and for enthusiasm for future implementation of Workshop recommendations. While our attendance was mostly North American, we appreciate that some participants, especially OECD Country and Secretariat representatives, traveled substantial distances to attend. We would like to take this opportunity to express our appreciation to each person who has made the Workshop possible and successful.

We extend sincere appreciation to Gail Charnley and Alan Krupnick for accepting and accomplishing, with excellence, the shared role of co-chairing the Workshop. Their leadership focused the Workshop discussions into articulate, actionable principles and recommendations.

We also thank Roger Tregunno for providing the Keynote Presentation encouraging collaboration and for contributing to our discussions. Roger, OECD Socio-economic Analysis Task Force Chair, and Richard Sigman, OECD Secretariat, have been advocates of this subject and supporters of the Workshop from the beginning. Des Mahon, Mary Ellen Weber, and Cristina Cortinas de Nava provided informative national perspectives. Paul Portney, luncheon speaker, provided a historical perspective and ideas for moving the issue forward.

We wish also to recognize the contribution of each member of the Workshop Planning Committee. In particular, we owe our gratitude to Lynne Blake-Hedges for drafting and redrafting the invitation and Breakout Discussion Topics documents, to Jean-Willy Ileka for drafting our guidance to discussion leaders, and Elizabeth Boa for logistical oversight. Lori Strong of Burk and Associates, Inc. provided much needed administrative and logistical support. We have all contributed with the backing of our respective sponsoring organizations.

Workshop Planning Committee
Elin J. Eysenbach, Chair, Procter & Gamble
Lynne Blake-Hedges, United States Environmental Protection Agency
Elizabeth Boa, American Chemistry Council
André Bourassa, International Council of Metals and the Environment
Jean-Willy Ileka, Environment Canada
Robert E. Lee, II, United States Environmental Protection Agency
Mark Lewis, Environment Canada
Arthur Sheffield, Environment Canada

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Workshop on the Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions took place in Arlington, VA, USA on 1-2 May 2000. It was organized and funded by the United States Environmental Protection Agency, the Government of Canada, American Chemistry Council, International Council on Metals and the Environment, Society for Risk Analysis, Resources for the Future and The Procter & Gamble Company, in co-operation with the Organization for Economic Co-operation and Development (OECD).

This Workshop was designed to bring together, by invitation, risk assessors, economists, policy-makers, and policy analysts to explore the needs and means for effective collaboration to support chemical risk management decision-making. The objective of the Workshop was to create links between risk assessment and economic analysis and examine possible solutions to issues of common concern. This goal was facilitated by:

- providing a framework for collaboration between risk assessment and socio-economic analysis in chemical risk management decision-making;
- sharing experiences and exploring commonalties and opportunities for collaboration across the disciplines represented;
- identifying barriers, discussing means to overcome them, and considering approaches that may enhance future linkages among the risk assessment and economic analysis roles within chemical risk management; and
- identifying areas that warrant further work or attention, considering the importance and immediacy of possible solutions, and suggesting means for carrying the work forward.

Participants were selected to achieve some balance among the risk assessment and economic analysis disciplines and included a number of policy-makers and policy analysts. The participants worked primarily from their own knowledge and experience and the experiences shared during breakout discussion sessions addressing three topics:

- Inputs and Outputs
- Issues of Evaluation Processes and Models
- Broadening the Assessment Approach.

Following, but not confined to, a set of discussion topic descriptions and questions, four parallel breakout groups explored these topics and generated ideas and recommendations that were then discussed in plenary. Breakout discussion leaders, one risk assessor and one economist for each group, introduced the topics from the perspective of their discipline and then lead the group through exploration of the discussion questions as described above.

The Workshop agreed that risk assessment and socio-economic analysis should be components of chemical risk management decision-making in both early and later stages, and that national

governments and OECD should take a leading role in fostering improved linkages between these disciplines within that context.

A series of principles and recommendations were agreed upon as a result of Workshop discussions. The principles provide context within which further work on the topic of the Workshop is likely to be most effective. They address the roles within the risk management process, information quality and timeliness, systematic approaches, adaptiveness, and assuring effort and expense commensurate with decision impact.

The recommendations suggest specific ways and means by which the sponsoring organizations or others may take action to enhance the risk management process. Action recommendations include development of case studies; meetings to further evaluate integration concepts; development of written, electronic, and analytical tools; and outreach through governments and professional associations. Process recommendations support the integration of cultural and other differences into the risk management process.

The report will be provided to OECD Member Governments for consideration at the November 2000 or June 2001 Joint Meeting of the Chemicals Committee and the Working Party on Industrial Chemicals, Pesticides, and Biotechnology.

INTRODUCTION

The Workshop on the Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions was conceived within the context of the Organization for Economic Co-operation and Development (OECD) Risk Management Programme under the auspices of the Joint Meeting of the Chemicals Committee and the Working Party on Industrial Chemicals, Pesticides, and Biotechnology. It provides progress toward fulfilling one of the recommendations from an earlier workshop that provided the basis for the current OECD Socio-Economic Analysis project. Other activities also have contributed to an understanding of the importance of resolving this issue, such as the United States Commission on Risk Assessment and Risk Management.

Canada, Mexico, and the United States offered to organize and host this Workshop to initiate work toward furthering national capacities for developing and effectively utilizing both risk assessment and economic analysis. Sponsors hope that the Workshop outcome will inform not only the risk management decision processes of the North American countries, but also those of other OECD countries and, indeed, future activities of the OECD Project on Socio-Economic Analysis. With the previous work, such as the OECD Socio-Economic Analysis Framework Document, as a foundation, the Workshop was able to maintain its intended focus on the link between the disciplines.

OECD Project on Socio-Economic Analysis

The OECD Project on Socio-economic Analysis was initiated to provide guidance to the Joint Meeting and OECD countries on the use of socio-economic analysis tools or techniques that could aid in risk management decision-making. To develop a beneficial path forward, OECD organized the Workshop on the Integration of Socio-economic Analysis in Chemical Risk Management Decision-Making (London, January 1998, see http://www.oecd.org/ehs/rskreprt.htm). That workshop, attended by almost 100 representatives from 18 OECD countries, the European Commission, industry and trade unions, brought together economic analysts and risk managers to review basic information, share experiences, and identify areas where further work was needed. The London workshop recommendations may be summarized as follows:

1. Develop a flexible framework for integrating socio-economic analysis into chemical risk management.
2. Establish a mechanism for sharing information regarding current practices among OECD countries.
3. Undertake retrospective studies to determine under what circumstances socio-economic analysis has influenced chemical risk management decisions.

4. Explore means to establish a mechanism for communication between risk assessors and economists.

5. Develop a protocol ensuring credibility of socio-economic analysis data when gathered through private means.

The OECD has completed and published a "Framework for Integrating Socio-Economic Analysis in Chemical Risk Management Decision Making" (2000) whose target audience is national chemical risk management policy-makers. That report provides an overview of socio-economic analysis tools and their applicability in chemical risk management. In addition, the OECD produced a "Guidance for Conducting Retrospective Studies on Socio-Economic Analysis" (1999) which discusses the practice of conducting retrospective studies to evaluate how socio-economic analysis has been used in chemical risk management decision-making and to extract lessons learned that would inform the design of future retrospective studies. Both of these documents can be downloaded for no fee from the OECD's public website (http://www.oecd.org/ehs/risk.htm under the heading "Work on Methods" and the section "Integrating Socio-Economic Analysis in Chemical Risk Management Decision-Making"). Furthermore, a Technical Guidance Document is expected to be completed in 2001. That document will provide a more detailed review of socio-economic analysis tools and specific guidance on their usage as gleaned from experience of the OECD national governments. The authors are planning to incorporate ideas from the present Workshop into a section on linking risk assessment and socio-economic analysis. All of these documents have been prepared with the able assistance of Ms. Meg Postle of Risk Policy Analysts, Ltd.

U.S. Commission on Risk Assessment and Risk Management

The need for linking risk assessment and socio-economic analysis has been recognized not only from the economic perspective, but also from that of the risk assessor and policy-maker as well. An important study, "Risk Assessment and Risk Management in Regulatory Decision-Making" prepared by the (United States) Presidential/Congressional Commission on Risk Assessment and Risk Management[2] (http://www.oecd.org/ehs/rskreprt.htm) has also addressed this need. In that report (p.99) the Commission recommends:

> "Risk assessors and economists who must rely on the results of risk assessments to estimate benefits should collaborate more to reduce the inconsistencies between scientific and economic approaches to characterizing risks and risk reduction alternatives. Risk assessors and economists should expand their methods to reduce mismatches."

The Commission report continues with thoughtful problem delineation that has served as a foundation of this Workshop.

[2] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making, Final Report, V. II. GPO #055-000-00567-1. Washington, DC (1997)

Further Initiatives

The topic of better utilizing both risk assessment and socio-economic analysis through collaboration and methods modifications is extremely timely. National and transnational government representatives have expressed interest in developing recommendations to enhance chemical risk management decision-making. This report provides an opportunity for national governments to consider the relevance of the ideas and to incorporate them as appropriate into new and ongoing risk management programs. For example, the USEPA Science Advisory Board indicated plans to address this subject at a workshop in the context of the Clean Air Act Hazardous Air Pollutants program. In addition, the OECD plans to use the Workshop output not only as an input to guidance development, but also in consideration of further steps within its Project on Socio-economic Analysis. Next steps for OECD are expected to include an evaluation of progress against the recommendations of the London workshop and incorporating ideas and recommendations from the present Workshop into future work plans. Opportunities for articles, posters, and presentations will be sought to communicate the recommendations of this Workshop through the Society for Risk Analysis, the Society for Environmental Toxicology and Chemistry, and other professional associations.

CO-CHAIRS' REPORT

Workshop on the Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions

Workshop Co-Chairs:

Gail Charnley, HealthRisk Strategies and Society for Risk Analysis

Alan Krupnick, Resources for the Future

Breakout Session Co-Leaders:

Group A - **Don Barnes** (Environmental Protection Agency, Science Advisory Board, United States)
Jack Donnan (Ontario Ministry of Energy, Science and Technology, Canada)

Group B - **Marc Saner** (Carleton University, Canada)
Sue Ferenc (International Life Sciences Institute, Risk Science Institute, United States)

Group C - **Tim McDaniels** (University of British Columbia, Canada)
Christine Augustyniak (Environmental Protection Agency, United States)

Group D - **Cristina Cortinas de Nava** (National Institute of Ecology, Mexico)
Peter Calow (Sheffield University, United Kingdom)

Rapporteurs:

Workshop **Lynne Blake-Hedges** (Environmental Protection Agency, United States)
Elin Eysenbach (Procter & Gamble, United States)

Group A - **Geoff Granville** (Shell Chemicals, Canada)
Richard Sigman (Organization for Economic Co-operation and Development, France)

Group B - **Gary Cole** (Environmental Protection Agency, United States)
Tom Muir (Environment Canada)

Group C - **Robin Hill** (Health Canada)
Tom Starr (TBS Associates, United States)

Group D - **Anne Sergeant** (Environmental Protection Agency, United States)
Martha Moore (American Chemistry Council, United States)

Organization of the Workshop

The Workshop on the Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions was organized in co-operation with the Organization for Economic Co-operation and Development (OECD) by an ad hoc committee requested by the Joint Meeting of the Chemicals Committee and the Working Party on Industrial Chemicals, Pesticides, and Biotechnology within the programs of Risk Management and Socio-economic Analysis. To fulfill recommendations of an earlier workshop in times of reorganization and budget restructuring within the OECD Chemicals Program, the Workshop was undertaken on an ad hoc basis as a regional project with international participation. It was organized by the United States, Canada, and industry representatives with funding, technical advice, and logistical support from the following:

- United States Environmental Protection Agency
- The Government of Canada
- The American Chemistry Council
- The International Council on Metals and the Environment
- The Society for Risk Analysis
- Resources for the Future
- The Procter & Gamble Company

Workshop Objectives

The Workshop was designed to bring together risk assessors and economic analysts to promote the integration of information from those two disciplines in supporting chemical risk management decisions by:

- Providing an understanding of the issues and barriers;
- Providing discussion questions as a basis for making recommendations for future work to resolve those issues; and
- Identifying areas for further work to resolve differences and suggesting means to carry out the suggested work.

Workshop Process

Participation

To ensure meaningful and credible recommendations, the sponsoring organizations attempted to achieve balanced participation with regard to technical discipline and organizational representation. As this Workshop intended to explore the needs and means for effective collaboration of risk assessors, economists, and policy-makers, the organizers attempted to bring together a balanced representation of those disciplines. The representation of risk assessors and economists was approximately 40% each with policy-makers and other stakeholders constituting the remaining 20%. Geographic representation was predominantly from the United States and Canada, with a few participants from Mexico and from European and Asian countries.

Pre-Work

In preparation for the Workshop, attendees were provided with discussion thought-starters on each of the three discussion topics. In addition, a "pre-work" package was distributed with background information including recommendations on the convergence of risk analysis and socio-economic analysis from the (U.S.) Presidential/Congressional Commission on Risk Assessment and Risk Management. References on risk assessment and socio-economic analysis, including glossaries, were also included so the participants could familiarize themselves with the other discipline.

Breakout Group Discussions

Prior to the Workshop, participants, two co-leaders, and two rapporteurs were assigned to one of four breakout groups with the goal of achieving balance in discipline and affiliation. Each breakout group examined three topics aided by discussion thought-starters. Discussion leaders (one risk assessor and one economist) for each breakout group guided their group through discussions on barriers to integration and means to overcome them. Using a matrix provided to them, groups were asked to distinguish between recommendations that may be acted upon in the near-term and those requiring more time and substantial resources, or those that are currently intractable. At the end of each session, the groups reported on their discussions to the plenary. The plenary of the Workshop discussed these ideas and drafted principles and recommendations.

Report Drafting

Members of the Workshop organizing committee and the co-chairs drafted a report based on the Workshop discussions and recommendations. The entire organizing committee then reviewed this report for accuracy. A subsequent draft was sent to Workshop participants, including the principles and recommendations, for their review.

Workshop Discussions

Summaries of presentations, visual materials provided by plenary speakers, and a compilation of ideas presented by the breakout discussion leaders and rapporteurs are provided in the body of the report. Prework and participant listings are provided in the Annexes.

Co-Chairs' Perspective

The Workshop Principles and Recommendations reflect the fundamental nature of and inherent difficulties in resolving the differences that have evolved in the processes, procedures, output formats, and priorities of the risk assessment and socio-economic analysis disciplines. While discussions from this Workshop offer general approaches that may lead to future resolution of some of the difficult issues, grappling with specific case studies and evaluating modifications of analysis approaches and methods will be necessary to make further progress. Maintaining the momentum of this Workshop will require the national delegations present at the Workshop and the Socio-economic Analysis Program of the OECD to commit resources. One project, that will be undertaken even before the completion of this report, was noted by Don Barnes (USEPA). A workshop scheduled for June 2000 by the USEPA Science Advisory Board, would consider case studies of existing risk assessments performed under the Hazardous Air Pollutants requirements of the Clean Air Act.

Future progress in resolving incompatibility issues and making both socio-economic analysis and risk assessment continually more relevant to effective government decision-making will depend on commitment and action. Broadening the base of both national and other OECD stakeholder participants will be needed to provide the effort required to work through the challenging issues addressed by these discussions. Encouraging appropriate professional associations to promote greater integration and follow-through on the Workshop recommendations will contribute substantially to the needed progress.

PRINCIPLES AND RECOMMENDATIONS

Drafted During the

Workshop on the Convergence of Risk Assessment and Socio-economic Analysis
to Better Inform Chemical Risk Management Decisions
May 1-2, 2000, Arlington, VA, USA

Risk management is a process that depends on collaboration and co-operation among risk assessors, economists, policy analysts, risk managers, and other interested and affected parties. Risk assessment includes both characterizing risk and characterizing the change in risk associated with risk management options. Socio-economic analysis includes an assessment of the costs, benefits, and other economic consequences of risk management options and the distribution of those consequences among affected parties.

The objective of the Workshop was to explore ways to create and improve links between risk assessment and socio-economic analysis in support of chemical risk management decision-making. Workshop discussions stressed that better collaboration would likely foster timely and more effective risk management decisions. Based on those discussions, participants created the following set of principles and recommendations that are meant to encourage better collaboration and integration among risk assessors and economists.

PRINCIPLES

1. Risk assessment and socio-economic analysis are tools for organizing and synthesizing information for risk management.
2. Risk management requires integrated information from policy analysts, economists, and risk assessors.
3. Better information is provided to the risk manager when integration of risk assessment and socio-economic analysis takes place throughout the process of risk management, starting with the problem formulation stage, rather than near the end of the process or not at all.
4. Integration is fostered when risk managers, economists, and risk assessors work together as a team over the entire iterative risk management process, incorporating opportunities to review and revise analyses, results, and decisions as needed.
5. Collaboration and integration are fostered when risk assessors and economists adapt their analyses to meet each other's changing needs and situations.
6. Risk management is more resource-effective when investment in risk assessment and socio-economic analysis is proportionate to the differential impact of the risk management options.

7. Having risk and socio-economic information available in a timely way, while maintaining quality, supports better risk management decisions.
8. Articulation of qualitative and non-quantifiable risks and benefits is improved through collaboration between risk assessors and economists.

RECOMMENDATIONS

Establish a steering committee to follow-up on the recommendations of the Workshop. Follow-up should include activities like:

1. Organizing workshops or meetings as needed for further progress on the topic of the Workshop.
2. Developing case studies illustrating how economic analysis and risk assessment have been used in risk management, including lessons learned.
3. Economists interviewing risk assessors and vice versa for in-depth process understanding, basing these interviews on the case studies, and reporting the findings at a workshop or meeting.
4. Writing a primer that works towards a common language and a better understanding of methods to improve integration of risk assessment and economic analysis.
5. Identifying opinion leaders and informing them of the advantages of integration of risk assessment and socio-economic analysis.
6. Widely reporting the outcome of this Workshop.
7. Encouraging each participating country to initiate a pilot risk management study that incorporates the principles identified in this Workshop.
8. Developing improved measures for cost effectiveness, e.g., measuring changes in population exposure per unit cost for different risk management options or addressing low-dose information needs.
9. Creating and maintaining a list-serve and/or website to continue the collaborative dialogue initiated in the Workshop.

The following recommended activities pertain to the risk management process:

10. Making risk management decisions, beyond chemical-by-chemical regulation, in the larger context of public health, ecological, cultural, and economic priorities, such that collaboration of risk assessors and socio-economic analysts may enhance the identification of additional risk management options and prevention approaches.

11. Creating or improving risk management processes or regulations by applying lessons learned from the experience of existing processes, especially by obtaining benefits from improved linkages between risk assessors and economists.

WORKSHOP AGENDA

Workshop on
the Convergence of Risk Assessment and Socio-economic Analysis
to Better Inform Chemical Risk Management Decisions

Agenda

May 1-2, 2000
Arlington, Virginia

Sponsored by: Government of Canada, American Chemistry Council, U.S. Environmental Protection Agency, Society for Risk Analysis, the International Council on Metals and the Environment (ICME), Procter and Gamble, and Resources for the Future; in co-operation with the Organization for Economic Co-operation and Development (OECD).

Within the risk management decision process, both risk assessment and economic analysis provide information to the decision-maker. However, each has evolved independently of the other and been designed to answer different questions. In addition to providing information of an independent nature, both analyses need to work effectively together to facilitate assessment of decision options, to effectively serve the decision-maker. This Workshop will explore the needs and means for effective collaboration of risk assessors, economists, and policy-makers to support chemical risk management decision-making.

The objective of the Workshop is to create and improve links between risk assessment and economic analysis in support of chemical risk management decision-making and examine possible solutions to issues of common interest. While previous efforts such as the *Organization for Economic Co-operation and Development (OECD) Workshop on the Integration of Socio-Economic Analysis in Chemical Risk Management Decision Making* (London, January 1998) and the (US) *Presidential/Congressional Commission on Risk Assessment and Risk Management* (Washington, D.C., 1997) have identified the need for improved linkages and the key topics of concern, this Workshop is designed to develop specific recommendations addressing several of those topics by which each community of practice may better contribute to effective chemical risk management decision making. Discussion topics have been selected that encourage a broad discussion of compatibility of what risk assessors and economists use for inputs and output, then focusing on details of how analyses are developed to obtain these products. Finally, the Workshop moves into a consideration of two aspects that broaden the scope of traditional products of socio-economic and risk analysis. An intended outcome of the Workshop is identification of barriers and enhancements to creating effective linkages, as well as possible recommended steps to overcoming those barriers. The Workshop report, including the recommendations will be provided to all participants and affected organizations, and also to the OECD for integration into its program on Socio-Economic Analysis.

To ensure meaningful and credible Workshop recommendations, the sponsoring organizations have attempted to achieve balanced participation with regard to technical discipline and organizational representation.

AGENDA

Day 1

8-8:30 am Registration

INTRODUCTION (Plenary Session)

8:30-9:00am Opening: The Roles of Risk Assessment and Socio-economic Analysis in the Risk Management Process and Opportunities for Linking the Two More Closely

Meeting Co-Chairs: Gail Charnley, Past President,
Society for Risk Analysis

Alan Krupnick, Senior Fellow and Director
Quality of the Environment Division
Resources for the Future

9:00-9:20am A Framework for Collaboration between Risk Assessment and Socio-economic Analysis in Chemical Risk Management Decision Making: Perspective of a Chemical Risk Management Policymaker

Keynote Speaker: Roger Tregunno
Chemicals and Biotechnology Division
UK Department of Environment, Transport and the Regions; also Chair of the Socio-economic Analysis Steering Team, Chemicals Program of the Organization for Economic Co-operation and Development

9:20-9:40am National Policy Perspectives: Canada, U.S., and Mexico

Speakers: Des Mahon, Associate Director
Commercial Chemicals Evaluation Branch
Environment Canada

Mary Ellen Weber, Acting Deputy Office Director
Office of Pollution Prevention and Toxics
US Environmental Protection Agency

Cristina Cortinas de Nava, Ph. D.
Director General of Dangerous Materials, Wastes, and Activities
National Institute of Ecology (INE), Environment Agency of Mexico

9:40-9:45am Directions provided for the breakout sessions.

9:45-10:00am Coffee Break

BREAKOUT DISCUSSIONS

Breakout Session Co-leaders

Christine Augustyniak, US Environmental Protection Agency	Don Barnes, US Environmental Protection Agency
Peter Calow, Sheffield University, UK	Cristina Cortinas de Nava, National Institute of Ecology, Mexico
Jack Donnan, Ontario Ministry of Energy, Science and Technology, Canada	Sue Ferenc, ILSI Risk Science Institute
Tim McDaniels, University of British Columbia, Canada	Marc Saner, Carleton University, Ottawa, Canada

10:00-12:00pm Breakout Discussion: Topic I - *Inputs and Outputs*

This will be a broad discussion of the types of inputs and outputs in socio-economic and risk analysis, what types of information these analyses need, where there are or are not overlaps, and approaches and barriers to obtaining or developing useful information for both analyses.

12:00-1:00pm Lunch

Speaker: Paul Portney
President
Resources for the Future

1:00-2:00pm Plenary Discussion of Topic I

2:00-4:00pm	Breakout Discussion: Topic II - *Building Scenarios with Mutual Applicability.* Both disciplines rely on methods, models, and assumptions to meet the needs of that discipline. However, when attempting to link information developed by the two disciplines, incompatibilities may emerge. This topic explores how scenarios can be built that link socio-economic and risk analysis to better inform risk management decision-making.
3:00-3:30pm	Coffee available. Breakout groups requested to take break as fits their discussion needs.
4:00-5:00pm	Plenary Discussion of Topic II

Day 2

8:30-9:00	Recommendations on Topics I & II, draft available. Participants requested to read it carefully in preparation for discussion.
9:00-9:30	Review and discussion of draft recommendations on Topics I & II
9:30-12:00	Breakout Discussion: Topic III - *Broadening the characterization of risk in option evaluation.* This discussion focuses on how risk and socio-economic analysis can bring information to the decision maker facing decisions involving many trade-offs among risk management options, encouraging participants to consider broadening the scope of more "traditional" risk and socio-economic analysis.
10:00-10:30	Coffee available. Breakout groups requested to take their break as fits their discussion needs.
12:00-1:00pm	Lunch Break
1:00-2:00pm	Plenary Discussion of Topic III
2:00-2:30pm	Coffee Break
2:30-3:30pm	Plenary discussion to agree on Recommendations from the Workshop
3:30-4:00pm	Closing remarks from Co-chairs

PAPERS PRESENTED AT THE WORKSHOP

(Note: Presentation materials have been provided by the presenters or noted from their remarks and do not represent opinions or policies of their organization of affiliation or of any other organization.)

The Roles of Risk Assessment and Socio-economic Analysis in the Risk Management Process and Opportunities for Linking the Two More Closely: Risk Assessment Perspective.

Gail Charnley, HealthRisk Strategies and Society for Risk Analysis

Good morning, and welcome to the first workshop that I'm aware of that seeks to address the need for convergence of risk assessment and socio-economic analysis to better inform chemical risk management decision-making.

The apparent disconnect between risk assessment and economic analysis in the context of chemical risk management first came to my attention during the tenure of the Commission on Risk Assessment and Risk Management. The Commission was tasked with evaluating the use of risk assessment and risk management in federal regulatory programs. At some point it occurred to us that it was difficult to evaluate the role of risk assessment in isolation from all the other factors that comprise risk management, economic analysis being notable among those. Of course, none of the risk commissioners was particularly qualified to opine on the role of economic analysis in risk management, but that certainly didn't stop us from doing so anyway.

Fortunately for the Commission, we were able to call upon the expertise of Resources for the Future and my co-chair today, Alan Krupnick, so that we didn't sound like complete idiots on the subject of economic analysis. Anyway, I am pleased to see that one of the Commission's recommendations in this area—that risk assessors and economists should collaborate more to reduce the inconsistencies between risk assessment and economic analysis—has finally come to fruition here today.

I'm mentioning the Risk Commission because I think our experience exemplifies the problem we're here to tackle today. Risk analysts know a whole lot about risk analysis and economists know a whole lot about economic analysis and although both provide important input to risk management, we don't seem to know much about each other's disciplines. We seem to operate in parallel universes, and while that situation may ensure that more of us remain employed than might otherwise, it also has led to some important disconnects in how we conduct our business.

For example, in risk analysis, we tend to rely on conservative assumptions to account for uncertainty about exposure or toxicity. That way, we purposely skew our risk estimates upwards to build in a margin of safety that is intended to be health-protective, that is, to protect most of an exposed population. We have traditionally communicated to the risk manager one point in the

upper end of the distribution of risks. By contrast, economic analysis describes the distribution of risk reductions across a population and leaves it up to the risk manager to decide what is an adequate level of protection and which risk management strategies deliver that level of protection.

Another example: In some areas of risk assessment, we are moving away from probabilistic analysis. As we do our best to incorporate "good science" into risk assessment, we have learned that assuming low-dose linearity is not always necessary for all chemical carcinogens. Assuming nonlinearity means using nonprobabilistic methods for assessing risk. In the international arena, nonprobabilistic approaches to assessing risk have been much more commonplace than probabilistic approaches for a long time. The problem is that assessing the benefits of risk management actions using economic analysis—in other words, characterizing expected risk reductions—depends on probabilistic characterizations of risk.

Risk managers, of course, have to weigh input from both risk assessors and economists to help make decisions, and it certainly would be helpful if we all used a common language. After all, using "good science" in risk management isn't restricted to the risk assessment component. The best risk management decisions depend on interactions among all kinds of different information sources and on good communication at all levels.

The past three administrations have issued executive orders requiring consideration of costs and benefits in regulatory decision-making. The Safe Drinking Water Act now requires consideration of costs and benefits in the regulation of drinking water contaminants. The general public is coming to realize that our resources aren't limitless and want economically responsible risk management. Optimal implementation of those mandates is going to require better characterization of both risks and benefits.

You know, we have picked most of the low-hanging fruit, risk management-wise, and as we move towards the top of the metaphorical risk tree, the role of economic analysis becomes more and more important in order to effectively evaluate the tradeoffs involved. Hopefully our efforts today will help facilitate that transition. We've got a lot of hard work ahead of us!

The Roles of Risk Assessment and Socio-economic Analysis in the Risk Management Process and Opportunities for Linking the Two More Closely: Economic Perspective.

Alan Krupnick, Resources for the Future

Dr. Krupnick provided insight into the importance of linking risk assessment and economic analysis in chemical risk management decision making from the perspective of an economist. He noted that strong participation from both disciplines provides a good indication of the need for and interest in better linkages. He introduced the Breakout Topics for the Workshop, referring to the prework material and explaining how the three topics had been organized. These topics were offered to Workshop participants as a good starting point to explore the opportunity for linkage and to go beyond that to discover effective mechanisms to improve linkages.

The issue of input and output is raised in Topic I. It inevitably leads to the question on the relevance of the information. For instance, how can one translate the information on dose-response function into something useful for the economist? Is it really the appropriate format for the economist to use? Just by this simple example we have an idea of the challenge facing the Workshop participants.

This example might be misleading as it conveys the impression that in the decision making process the information is going one way (i.e. from the risk assessor to the economist). In fact there should be, and there is a two-way interaction between both professionals. Information required for cost-benefit analysis (CBA) or the output for the economist, would be more meaningful when both sides have a good understanding of what each other can offer. A sort of mutual education will certainly be beneficial. Working on CBA, for the economist, not only would be seen as examining the effect of risk reduction, but also would be seen as the opportunity for the risk assessor to examine the question of substitution risk analysis. That is, working on CBA would provide opportunity to examine possibilities that behaviors linked to the regulation, such as substituting an unregulated chemical for a regulated one, may increase risks, mitigating or even offsetting the benefits from the regulation. The economist is particularly concerned that outputs from risk assessors should address population risks, central tendencies of risks, and appropriately define health endpoints for valuation.

With Topic II, even if the models and processes used by risk assessors and economists differ, risk assessors have a stake in good benefits analysis. In fact, Dr. Krupnick has argued (in his paper *Cost-Benefit Analysis and Regulatory Reform*) that from an economic perspective, risk assessment is a subset of benefit analysis. Therefore, there is a shared responsibility which ultimately has an impact on the society and thus on social welfare.

The major role for economists is introducing the idea of costs and tradeoffs into regulatory deliberation. In addition, he noted that while it is important to have a good characterization of

risk, the traditional upper-bound assumptions may warrant examination, as it is expected risks that are needed for a benefit analysis. In addition, economists and risk assessors should address the issues of lay perceptions and expert assessment of risks to reduce uncertainty. This largely ethical problem lies at the heart of many controversies over appropriate regulatory behavior. He noted that setting a realistic baseline, particularly one that continues into the future, is a necessary part of a credible analysis. He also highlighted the need to characterize uncertainties, through Monte Carlo analysis or other, less quantitative techniques.

Topic III on broadening the risk management approach should remind us all along of the omnipresence of the decision making process. CBA can assist in measuring the change in the welfare induced by policy decisions. Consequently, it has the potential to improve policy decisions. However, such decisions cannot rely only on the monetization of costs and benefits. The use and the development of alternative measures of health benefits should be encouraged. The quality adjusted life years (QALY) is an example of such an alternative measure that may have promise.

The role of alternative measures in the decision process might help to clarify the options, by providing better explanation of how the results were derived. It might also assist in identifying (and hopefully reducing) uncertainties while enhancing the transparency in the decision process. For risk managers there would be the prospect of well-conceived decisions. However, this can only be achieved if both disciplines work together and understand better each other. Dr. Krupnick pointed out that this would require participants to engage in a lot of work in the two days of the Workshop.

Issues in Improving Risk Management

Alan Krupnick
Resources for the Future

I. Inputs and Outputs

Risk Assessment (RA) <=> Cost-benefit analysis (CBA)

- RA=> CBA: Following the conventional air pollutant model
  - Population risks/central tendency
  - Probabilistic perspective/continuous CRFs
  - Appropriate "health endpoint" definitions
- RA <= CBA: Substitution risk analysis

II. Models and Processes

Big Picture Concepts

- Social welfare maximization is "a" goal
  - role for cost
  - expert vs. lay risk
- Prioritization of regulatory activity
  - baselines -- temporal elements
- Conservatism vs. characterizing uncertainty (statistical/ model)

III. Broadening the Risk Management Approach

-
- Scenarios
- Alternative measures of health benefits:
  - Quality Adjusted Life Years (QALYs)
  - risk attributes
- Scorecard

A Framework for Collaboration between Risk Assessment and Socio-economic Analysis in Chemical Risk Management Decision-making: Perspective of a Chemical Risk Management Policy-maker.

Roger Tregunno, United Kingdom Department of Environment, Transport and the Regions

Although I am here as a policy-maker, I have worked as a chemical engineer in industry, a government factories inspector and subsequently in various policy jobs on health, safety and environment. I can't claim to be a scientist or an economist, but I now rely on their output more than any other disciplines. My interest in chemicals assessment and management started around 11 years ago both in the EU and OECD. It seems increasingly to be the case that this work is becoming international so I regard meetings such as this which aim at a better common understanding of the decision making process to be vital to promoting the most efficient use of scarce resources both in governments and industry.

Work in the UK on developing a European approach to risk/cost benefit analysis (as it was then called) started as a result of a few words in a European Regulation which required 'an analysis of the advantages and drawbacks of the substances if this involved restrictions on marketing and use, and of the availability of replacement substances'. We set up an industry/government working group (which was in fact chaired by a member of this audience, Peter Calow) to produce guidance on this task and the UK subsequently won a contract to produce EU guidance on the same subject. Many of you will be aware of the recently published OECD Framework Document for integrating Socio- Economic Analysis in Chemical Risk Management Decision Making which was also sponsored by the UK. This document resulted from an OECD Workshop in London in 1998 which was also the catalyst for this meeting.

In the UK, there has been a steady progress since the early 1990s' in developing, applying and refining policy appraisal techniques. A fair, decent and safe society depends on good regulation. People look to their Governments to ensure that they receive benefits such as a cleaner environment and safer products. But precisely because issues like these are so important to us, it is vital that we act wisely and ensure that proposed actions are based on a clear understanding of the risks, costs, benefits and those who will be affected. Any proposals in the UK that require the introduction of regulations have to be supported by such an analysis.

Chemicals risk management is, for most countries, a policy driven process in which concerns are raised through an assessment of risk to health or the environment by scientists. The actions needed, if any, to address identified risks can involve a range of measures from labeling of products through to bans or severe restrictions on use. The severity of a particular measure or measures will depend upon a range of factors such as level of concern, the potential for a serious effect being realised and the socio-economic consequences. Ultimately, we cannot ignore the possibility of an overlay of political judgement. Getting the right balance between all these potentially conflicting factors is never straightforward.

So what are the practicalities of such a process? I will briefly describe how things have worked up to now in the EU – I think you will then appreciate why the output of this meeting could be important. Our system is basically sequential involving nomination of priority chemicals for risk assessment by Member States (6 months) followed by data gathering by industry (up to 18 months). The lead Member State then carries out the risk assessment (1-2 years) and seeks agreement with other Member States (at least 1 year). After agreement (and we're already up to 3-4 years) the risk assessment is handed to policy-makers for consideration of the need for risk reduction action. If marketing and use restrictions appear to be a likely option, a SEA must be prepared and then agreed by all Member States. This can take a further year – or even longer, because by this time the use pattern of the chemical has probably changed, the quantity on the market has changed, the scientists may have changed and sometimes, even the manufacturers have changed. Furthermore, the type of information gathered for the risk assessment may not be in a form that is consistent with the needs of risk managers. We do not want to have to revisit the risk assessment data as part of the SEA, but risk managers must have the necessary information to work with. Therefore, should we have started the SEA earlier to amend these problems? Probably! By now, politicians will understandably be getting impatient. They will have read about concerns around the chemical in the environmental and sometimes national press and they want action – yet we could still be a long way from a supportable risk reduction strategy for either health or environment. This inevitably results in pressure to take action without proper understanding of the science, but we can't afford to wait 5 years or more before concluding on the need for measures where there is potential concern for human health or the environment.

So what can be done? How can we speed up the process? Risk assessors are concerned that science should not be compromised by economic or political considerations during the risk assessment – but assessors must accept that their work only need go as far as is necessary to make a decision on risk management. But how do we decide when this is? How do we deal with the issue of substitutes for the chemical of concern? We must ensure that the work on the risk assessment is fully compatible with the needs of risk managers. If we are to make the risk assessment more compatible with the needs of risk managers and economists do we need an output that enables direct comparison with the costs of the proposed measures? This is not something that is currently possible in the EU due to the generic nature of the risk assessment conclusions. Perhaps there is a role for OECD here? These are the problems that we're wrestling with in the UK at present.

Our risk assessments are carried out according to EU Technical Guidance by contractors managed by our Environment Agency and are then peer reviewed by independent scientists. This is to ensure that the assessment outcomes are as independent of Government as possible. There are 3 possible outcomes to an assessment, that the chemical is a low priority for further work, that more information is needed or that it is a candidate for risk reduction. Although the assessment is a long process, it is often clear early on that risk reduction may be necessary. It is at this stage, by regular contact with our Environment Agency that we can decide when early application of an SEA is likely to be helpful, both to the risk assessors and the risk managers. The SEA, too, is carried out by independent contractors managed by my policy unit. The brief, simply is to produce options, and a recommended, risk reduction strategy for the chemical concerned in

accordance with EU Guidance. In order to manage such a contract, a steering group of up to 12 stakeholders is established, chaired by a representative from my policy unit. Each steering group is designed to give best advice on the chemical under consideration but will contain our contractors for risk assessment and SEA, industry manufacturers and users, relevant Government departments, NGOs, other EU countries who we perceive to be our fiercest critics and our Department's economists who act as peer reviewers. The objective is to make the whole process as independent of Government and as transparent as possible whilst producing as robust a proposal as we can. The work is still in its early stages. We have completed 3 risk reduction strategies so far (SCCPs, Nonylphenol, Pentabromodiphenyl Ether). But we are already finding the need to better integrate our assessment processes to speed up decision making.

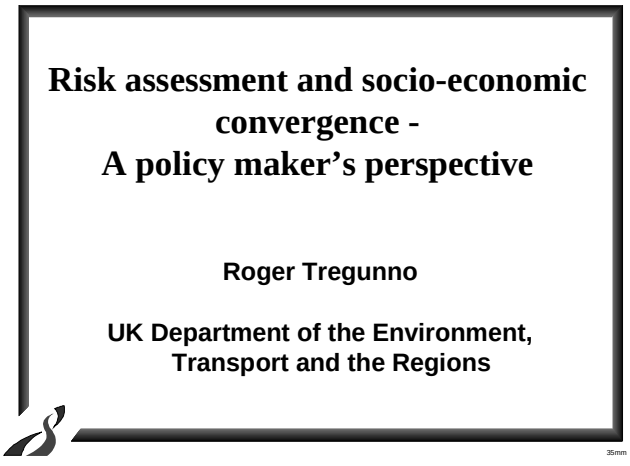
We find that work carried out by our SEA contractors leads to further queries on the risk assessment. But we haven't concluded that we should integrate the risk assessment and SEA. An SEA will define and qualify the best actions necessary to meet concerns raised by the risk assessment – it will not change the scientific advice. Nonetheless we believe that by bringing those with an interest in a chemical together, we will promote a more holistic approach to chemicals risk management and a better appreciation of the needs and concerns of all participants in the process, not just those in the scientific and economics communities. This is also an important theme in our recently published Chemicals Strategy for the UK, as a result of which we will soon be setting up a Stakeholder Forum on chemicals which will address both the assessment and management of risks from chemicals in an open and transparent way.

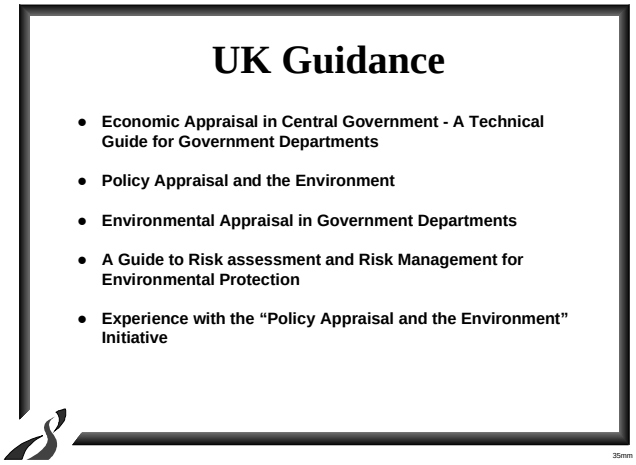
As I alluded to earlier, this work is to meet the requirements of a European programme and outputs on both the risk assessment and SEA are presented by our contractors at European scientific and risk management meetings. Although this policy carries a risk that the output will not accord with our policy objectives, we have found so far that the benefits conferred by transparency far outweigh the risks – though we haven't yet quantified them! I have no doubt that our co-ordination of experts in making policy decisions will improve with experience but we are convinced that early contact between risk assessors and economists will help. Common data sources can then be accessed concurrently in a complimentary way and a better understanding developed of how the whole process of risk assessment, SEA and policy making fit together. Burdens will also be reduced on those providing the data and unnecessary duplication avoided. This teamwork could also be vital in helping the policy-maker decide when precautionary action is needed – a decision that requires adequate information just as any other does. Having presented our work both in the EU and OECD, I believe that the issues we have faced are just the same here as in the UK.

Key elements for risk management decision making are good scientific advice that includes confidence limits, options for risk management that include the effectiveness of each option, and their economic consequences. But most of all, this information needs to be presented in a timely fashion to meet political imperatives. Without good co-ordination of the key elements it is difficult to see how the process can operate at an acceptable speed. But failure may well lead to more and more action being taken on a less than sound basis – so the price of failure could be high.

As a policy-maker, my perception is that the risk assessor always needs just a little more information to better characterise the risk. The economist, on the other hand, requires just a little more quantification in order to better define costs and benefits. I, meanwhile, need sufficient information in terms of risk assessment and SEA, as soon as possible, in order to decide whether I should recommend risk management and if so, what those measures should be and what are the consequences. How best to manage these elements is vital to better decision making but probably involves ownership by all of the final outcome of the work or at least recognition of the contributions of all concerned

I should like to finish with what has become a pet subject of mine. We all take some comfort from the language of our club. Be we risk assessors, economists or policy-makers we all talk in a short hand that can exclude others. My plea is that we try to make our specialist languages inclusive rather than exclusive so that our work is as transparent to non-experts as it is to experts. Perhaps then the benefits of an integrated approach will be much clearer to those assessing and managing risks from chemicals. That, ladies and gentlemen, is a challenge to us all.





The Challenges

- How can we speed up the process?
- How do we decide when to begin SEA?
- How do we ensure compatibility between risk assessment and SEA output?
- What is the role of OECD?

35mm

Risk Assessment

- Prioritisation (6 Months)
- Data Gathering (18 Months)
- Risk assessment (12-24 months)
- Agreement with Member States (12 months)
- Socio-economic analysis (12 months)

35mm

Risk Reduction Strategies

- Risk assessment conclusions
- Risk reduction Steering Groups
- SCCPs / Nonylphenol / Penta-BDPE
- Stakeholder Forum

35mm

What do we need to achieve?

- Transparent decision making
- Early contact between risk assessors and economists
- Team working to deliver timely and complimentary output
- If we fail?

35mm

National Policy Perspective

Des Mahon, Canada, Environment Canada

Des Mahon stressed the need for risk assessors and economists to communicate early and often in the risk management decision-making process. What is really important is the need for a mutual understanding of endpoint and uncertainties by each profession. What are some of the other problems - lack of knowledge of the requirements for each process, lack of informed consideration of the methodologies used in each discipline and how to address the inherent uncertainty in each of the methodologies used when considering a recommendation. In Canada, there isn't the need to look for a new process, but rather to improve the output from the process. Better coordination, integration and information sharing coupled with timely and appropriate information collection is what the future holds.

CONVERGENCE OF

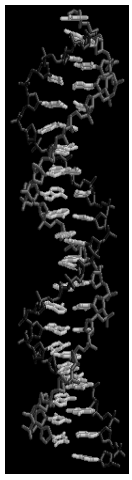
RISK ASSESSMENT AND SOCIOECONOMIC ANALYSIS

CANADIAN PERSPECTIVE

Commercial Chemicals Evaluation Branch
Environment Canada

Environment Canada Environnement Canada

1



LEGISLATION

Canadian Environmental Protection Act s 64:

..is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
a) have or may have an immediate or long term harmful effect on the environment or its biological diversity;
b) constitute or may constitute a danger to the environment on which life depends; or
c) constitute or may constitute a danger in Canada to human life or health

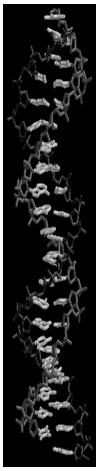
2

DECISION MAKING

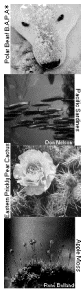
DECISION
Informed by 3 Elements

Risk assessment	**-**	**toxic**
Risk Management	**-**	**reduce risk**
Socio-economic Analysis		**cost benefit**

3



RISK ASSESSMENT



Toxicology
- **Data from industry**
- **Information from monitoring**
- **Information from national and international sources.**

Exposure
- **Data from regulated community**
- **Monitoring studies**

.

4

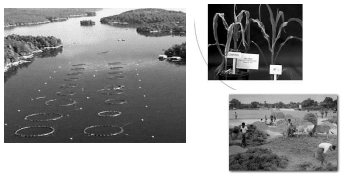
SOCIOECONOMIC ANALYSIS

Impact on Human Health:

- valuation
- costs benefits

Impact on the environment:

- valuation
-cost benefits



5

OUTCOME

1. Better coordination and integration.

2. Mutual understanding of the "end points" for each discipline.

3. Better understanding of the methodological limitations in each discipline.

4. Understanding the relationship between uncertainties in the decision making process.

6

National Policy Perspective

Mary Ellen Weber, United States, Environmental Protection Agency

I am delighted to be here today to encourage a deepening dialogue between risk assessors and economists. For several decades economists and risk assessors have played roles in the development of chemical risk management decisions but often without communication or coordination, and sometimes as adversaries. But before I talk about communication between economists and risk assessors, I want to tell you a bit about the evolution of the role of economic analysis in social regulation in general and in chemical risk management in particular in the United States.

In the United States under a series of Executive Orders the costs of social regulations and their merits had to be discussed as early as the 1950's under direction from the Eisenhower Administration. Subsequent administrations refined the demands for cost information, going from strictly engineering costs imposed on regulated firms by Government interventions to broader social costs born by society as a whole. They also added the requirement that the merits of the proposed regulations be described and even quantified to the extent possible. In the early years, economic information and considerations came in at the end of the risk reduction exercise only to help determine the least-cost alternative for a level of protection that had already been set by the risk assessors and policy-makers. The analyses of effects or benefits were done qualitatively or at most quantitatively, e.g. cases avoided, lives saved, changes in blood lead levels, pounds of mercury released to the environment. The discussion was in terms of costs per case avoided. From the Carter Administration in the late 1970's forward, Cost-Effectiveness, and later Cost-Benefit Analyses have been mandated by Executive Orders as an element to inform decisions on the appropriate levels and methods of protection or risk reduction. Once a target level of protection was decided, then cost effectiveness analysis could be used to assess alternative means of achieving the goal. Cost-Benefit Analyses can compare alternative levels and kinds of risk reduction. These “apples to oranges” comparisons require the use of a common metric, such as dollars. Cost-Benefit Analysis can give decision-decision makers an understanding of the linkages between the causes of the risk and the effectiveness of alternative options in reducing risk. While some environmental and health related statutes specifically preclude the use of Cost-Benefit Analysis to determine the levels of protection, the analyses may be done during or even after Agency decision making to set a context for the governmental intervention. In addition, the analyses must be presented to the President’s Office of Management and Budget as information in the rule making packages.

Economic analysis provides information on the distribution of risk and on the feasibility, costs, and effectiveness of alternatives and also on who pays and who benefits under different scenarios. Which brings me to the interaction between risk assessors and economists. The economist can help identify the size, composition, and distribution of the affected population and the impacts of different technological and work practice or design options for addressing risks. The risk assessor can use that information, especially that about exposures, to estimate risk and

the potential for reducing risk. The health scientist estimates toxicity and potency of the chemical. The exposure assessor estimates the affected population's exposure and that, in combination with the hazard assessment, leads to the risk assessments under different scenarios. The process must be interactive, iterative and ongoing to provide the effects information necessary to inform the decisions and result in an array of options for the decision-decision maker.

When the economist and risk assessor work together there are opportunities for targeting resources to maximize the efficiency of our risk reduction efforts. The policy-maker will want insight as to which kind of intervention is likely to be most effective, i.e. will people do what they need to do and if not what kind of policy would cause the desired response, and what are the anticipated effects of that policy. For example, in the case of blood lead poisoning in children, the economist can help determine where the children are, their age, racial, ethnic, and income groups, the kinds of housing in which they live, the costs to their parents or landlord of various kinds of lead removal or encapsulation, the likelihood of the housing remaining available vs. being torn-down or rents raised, etc. The scientist can relate changes in the lead concentration in soil dust to changes in blood lead to changes in intelligence quotient or hypertension. Then, the risk assessor can combine the information to estimate the number of cases of health effects expected at various levels of lead in soil. With that information, the economist can describe the costs to society of these physical decrements and the willingness of people to pay to avoid the pain and suffering associated with poorer quality of life. The economist can not, however, do much with information on lead levels in soil without the levels being related to kinds, severity, and frequency of describable health impacts.

Gail Charnley's observation about the policy implications of the way information is gathered and presented by risk analysts versus economists is absolutely crucial to an enhanced understanding between the two groups. Single, conservative, high-end point estimates of risk with or even without voluminous caveats skew the policy decision in a way that the policy-maker may not fully appreciate. On the other hand, the practice of economists to provide information on a range of alternative levels of protection across an array of people and with a number of means of achieving those levels comes with layers of assumptions intermingled with extrapolations and empirical data that may make choices seem more concretely differentiated in the eyes of the policy-maker than the underlying data really support. In addition, others have correctly noted that sometimes we actually are speaking the same language and accepting of the same philosophy of protection but hiding behind the walls of our different professional jargons.

In closing, I am gratified that risk assessors and economists have reached the stage where they do value the opportunity to understand better each other's potential contributions to risk reduction and to open the lines of communication so that the information they prepare for each other is timely and described and denominated in ways most useful to the recipient rather than for the convenience of the provider!

National Policy Perspective

Cristina Cortinas de Nava, Mexico, National Institute of Ecology

Mexico became a member of the OECD and subscribed to the North American Free Trade Agreement in 1994. Before that, it was considered as a developing country taking into account problems that have not yet been solved, such as the extreme poverty of important sectors of the population and poor basic sanitation influence in public health.

The industrialization process started in the 1940's and evolved rapidly introducing problems related to chemical management.

Regulation of chemicals takes place through several legislations that cover aspects related to public and worker's health as well as environmental and other issues.

The environmental legislation requires the assessment of the risks of accidents on installations that manage high volumes of hazardous materials and has not covered other risk aspects.

Since 1992, the Federal Law on Metrology and Standards makes mandatory the use of cost-benefit analysis to assess the regulatory impact of obligatory norms.

At present, a Regulation on Chemicals, Hazardous Wastes and High Risk Installations is being developed at the Ministry of Environment, Natural Resources and Fisheries that will address the issue of the risk assessment of chemicals and chemical management.

To learn from experiences of other OECD countries related to the challenges posed by risk assessment requirements and the application of socio-economic analysis to orient risk management decisions is key to Mexico, in order to avoid errors that have been experienced by other countries and to learn from successful approaches.

To give an example of problems that require the integration of socio-economic analysis in the assessment and management of chemical risks, a brief description of a Regional Action Plan to eliminate the use of dichloro diphenyl trichloroethane (DDT) in Mexico is presented. Consistent with its resolution to support the Sound Management of Chemicals from the Rio Convention, 1992, t This plan is being developed under the framework of the North American Environmental Co-operation Agreement subscribed to by Canada, Mexico and the United States and a resolution for the same Management of chemicals.

In Mexico, around 60 % of the territory was in the past a malaria region, where at present, more than 40 million inhabitants live and the most important economic activities take place. In the 1940's, around two million people had malaria and thousands of them died from the disease.

Through a very complex and successful program to control the transmission of the disease, as well as the involvement of important human and economic resources, the problem of malaria has been reduced to several endemic areas where DDT was applied indoors, only in homes where sick people lived.

Taking all these factors into consideration, Mexico agreed to develop the Regional Action Plan to eliminate the use of DDT, since Canada and the U.S. didn't use it anymore.

The Plan considered an 80 percent reduction in 5 years and the possibility of keeping stocks of DDT for 5 additional years in case of losing the control of the transmission of the disease. It also involved the study of cost effective alternatives that could allow the sustainability of the Malaria Control Program, taking into account that the cost of alternative chemical pesticides could be 3 to 10 times higher and require more applications.

Two additional problems were considered; the fact that after the occurrence of hurricanes, the conditions for the spread of malaria are created, making necessary the control of vector mosquitoes and the problems related to migration of workers from Central American countries affected with malaria.

This Plan is developed with the support of the North American Environmental Co-operation Commission and is going to be funded by the Global Environmental Fund (GEF) to cover actions to include Central American countries. The Ministry of Health of Mexico has announced that DDT is not used anymore and the industry located in the country that produced it has eliminated its production. Nevertheless, as the Plan stated, that Mexico will resume use of DDT in case of loss of control of the transmission of malaria using the alternative pesticides.

This example is a clear situation where the socio-economic analysis is needed to orient decisions to develop sustainable approaches to manage chemicals, and this case could be used to put into perspective the risks of a chemical taking into account other associated risks.

Luncheon Speaker

Paul Portney, Resources for the Future

Dr. Portney spoke about the evolution of economics in policy making in the U.S. from the early days, i.e., from the Nixon administration, through the present time period and then briefly speculated on the next 50 years. In the early part of the 1970's, in the Nixon and Ford administrations, regulatory oversight included first a "Quality of Life Review" and then an "Inflation Impact Analysis." While those approaches were beginning to address the economic questions about effects of regulatory decisions on individuals and on the economy, it wasn't until the Carter administration in the late 1970's, that benefit-cost analysis of regulations was explicitly required. This requirement was implemented by executive order from the president and enforced by the newly formed Regulatory Analysis Review Group operating out of the Council of Economic Advisors . At the beginning of the Reagan administration in the early 1980's, the requirement for benefit-cost analysis was strengthened and oversight moved to the newly created Office of Information and Regulatory Affairs in the Office of Management and Budget. This requirement and oversight arrangement continued through the Bush Administration and on through the Clinton administration, although this latter administration added consideration of equity effects to the efficiency analysis (benefit-cost analysis) of previous administrations.

He also spoke of some of the legislative pressure during the 1990's for increased consideration of the economic effects of regulatory actions. He noted passage of the Unfunded Mandates Reform Act, which called for the assessment of impacts of federal regulation on state, local, and tribal governments. He also mentioned the Small Business Regulatory Enforcement Fairness Act. This act reinforced the Regulatory Flexibility Act's requirements to assess the economic impacts of regulations on small entities. It also provided for more direct congressional oversight to assure that these assessments are performed in a manner acceptable to Congress. In addition, he addressed the Food Quality Protection Act, which, among its provisions, replaced the zero-risk Delaney clause with a more balanced approach to addressing tradeoffs.

Dr. Portney spoke of the evolution of the concept of risk management, starting from a watershed speech by USEPA Administrator William Ruckelshaus in 1983, when, in a speech at the National Academy of Sciences, he popularized the concept of thinking distinctly about risk management, risk assessment, and risk communication. Those concepts were explained in a book published by the National Academy of Sciences in 1983, commonly referred to as the "Red Book."[3] Ruckelshaus' speech was the first real recognition of the importance of managing environmental risks rationally, and of the need for decision-makers to be asking questions about the extent of risk reduction and cost when considering environmental actions. In 1987 and 1990 the USEPA

[3] National Research Council, (National Academy Press, 1983), Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences. *Risk Assessment in the Federal Government: Managing the Process.*

published two reports, *Unfinished Business*[4] and *Reducing Risk*[5], which broadly identified the larger and more important environmental risks facing the country at that time. More recently, the US EPA Science Advisory Board formed a series of committees, some addressing risk assessment issues and others addressing economic issues, as part of an integrated risk project to explore procedures for better integrating ecological and human health risk assessment with economic assessment for the purpose of environmental decision-making.

In further comments, Dr. Portney suggested that statutes that prevent the use of benefit cost analysis are ill-considered. People need to understand that benefit-cost analysis provides important information in the decision process. It helps organize and convey information about the efficiency of various choices available to a decision maker. Yet, at the same time, people need to understand that it is not a sufficient basis alone for making a decision. Some legislators, such as Senator Thompson from Tennessee and Senator Levin from Michigan, have been trying to enlarge the role of benefit-cost analysis through regulatory reform legislation. Others seem to feel it is a "tool of Satan."

Dr. Portney suggested that economists and risk assessors must strive to work together and to find a common language. Both need to work together to structure analyses to help decision-making. Economists can not speak about health or ecological effects without risk assessment inputs. Consequently, they can not conduct benefit-cost analysis of those issues without risk inputs. Economists help by estimating the public's valuation of benefits, by handling different timing of benefits and costs, and by describing effects in terms the public can relate to. Integration of these disciplines is crucial to further improvement in the rational management of chemical risks.

"Where to" in the next 50 years? Dr. Portney sees expanded use of economic incentives in environmental regulation in the future. These allow for more individualized adjustments to fit specific circumstances, leading to more efficient solutions to environmental problems. He also sees more information-provision programs in the right-to-know vein. Starting in 1986 with emissions reporting on a specific list of chemicals from certain industries, public reporting of annual emissions has expanded to additional chemicals and industries at the national level in the U.S. It has also expanded to some state and local governments in addition to appearing in developing countries. This trend is expected to accelerate in future years. A third trend predicted by Dr. Portney is decentralization of environmental decisions to lower levels of governments on the one hand and more international negotiations of environmental standards on the other hand. Some problems, such as location and management of solid waste sites, are local problems with local effects, so it makes sense for their environmental effects to be managed locally.

---

[4] USEPA, Office of Policy, Planning and Evaluation, (EPA/230/2-87/025A), Unfinished Business: A Comparative Assessment of Environmental Problems: Overview Report,1987.

[5] USEPA, Science Advisory Board, (EPA SAB/EC-90/021), Reducing Risk: Setting Priorities and Strategies for Environmental Protection, 1990.

Other problems, such as climate change, have effects across national boundaries and need to be managed internationally if they are to be addressed successfully. Those wishing to explore these issues further may want to refer to a recent article, "Environmental Problems and Policy: 2000-2050," published by Dr. Portney in the Winter 2000 issue of the Resources for the Future quarterly publication, *Resources*.

BREAKOUT DISCUSSION SUMMARIES

This section is a consolidation of ideas reported from the discussions held by the four breakout groups for each of the three discussion topics. It is neither a verbatim transcript nor a record of the Workshop or breakout group consensus views. Rather, this summary is a means of retaining for future reference the breadth and variety of viewpoints expressed by members of the four breakout groups contributing to the Workshop outcome.

The discussions in the breakout sessions provided insight and enlightenment into the considerations and requirements of the two disciplines and resulted in the identification of the concepts leading to the Workshop "Principles and Recommendations". Several additional ideas selected from the breakout discussions may also serve as a basis for further discussion or research on the integration of the work of economists and risk assessors. In hopes that useful ideas from the breakout discussions will not be lost, but rather will be considered in future thinking, the Workshop Planning Committee has provided key concepts below, supported by a more detailed listing of breakout discussion ideas:

- Toxicological research better designed to provide information relevant to the characterization of dose-response, particularly in the low dose range;

- Approaches for handling uncertainty including probabilistic assessments and use of conservatism.;

- Approaches for valuing costs and benefits that do not rely on monetization;

- How can expert judgment be developed and used, e.g., "what-if" scenario development, lexigraphic techniques, dominance ranking;

- Making more use of qualitative information available in risk assessments.

Topic I - Inputs and Outputs

This session explored incompatibilities among the types of inputs used and the outputs developed by the risk assessment and economic analysis disciplines.

Cross-Disciplinary Understanding

Gaps in cross-disciplinary understanding of risk and economic assessments were identified. Compiling a bibliography of important books and articles in environmental economics, ecological economics, risk assessment, and chemical risk management may be a useful tool to improve cross-disciplinary understanding. Contributing to the gaps were misunderstandings

regarding terminology, e.g., population estimates, baseline analysis, margin of exposure, etc. and an incomplete understanding of the roles and techniques of the two disciplines. These may warrant clarification. One suggestion was to develop a primer or guidance document that could include an introduction to the two types of analyses and definitions of terms used. Reference to the discipline-specific glossaries provided as prework may assist in bringing more clarity or understanding.

Contributing were misunderstandings regarding terminology and incomplete understanding of the roles and techniques of the two disciplines. For instance, the human health risk assessor may interpret population estimates to be the risks to members of the general population (as opposed to workers, for instance) while the economist may be interpreting a population estimate to be the total number of cases of a health effect expected. These may warrant clarification. One suggestion was to develop a primer or guidance document that could include an introduction to the two types of analyses and definitions of terms used. Another was to compile a bibliography of sources used in environmental or ecological economics, risk assessment and chemical risk management.

Brief descriptions were provided by discussion leaders to introduce the disciplines to those of the other discipline or otherwise less familiar. Some participants perceived risk assessment as a means to describe the nature of a problem. Some risk assessments focus exclusively on a critical exposure pathway or primary effect.

Different practices among types of risk assessment may be a source of confusion. For instance, ecological risk assessment typically addresses population effects, whereas human health risk assessment characterizes individual risk. Thus, when considering inputs and outputs, some the Workshop participants indicated that the different types of risk assessment should be considered independently.

The economic analysis was described as one means to evaluate the consequences of risk management actions. These analyses make comparisons on the basis of costs and benefits to help characterize how efficiently the limited resources have been allocated. Economists define the benefits of an action as the expected risk reduction, such as decreased risks of cancer. In their analyses, economists attempt to monetize as many benefits as possible to facilitate a comparison with costs. To assess the benefits of an action, economists examine both a baseline status, i.e., risks under current conditions, and what change is expected when an action is implemented. The economist generally is interested in how all effects of a chemical might be changed by an action rather than focusing on a single primary effect.

Inputs and Outputs Useful to Economists and Risk Assessors

Session participants noted that risk assessors and economists may develop information that could be useful to each other and discussed some specific instances which are shown below.

Risk assessment information of potential use to economists:

- a description of threshold effects explaining why the selected endpoints are significant
- translations of risk quotients or upper bounds on risk estimates into risk distributions or characterizations of central tendency
- explicit identification of anything that is subjectively valued
- descriptions of the sources of relative uncertainty associated with risk estimates for each endpoint
- more dose-response and exposure data (this is desired for all endpoints and for addressing both human and environmental risks)
- more descriptive estimates of effects where it is not possible to quantify effects
- clearer characterization of health consequences and the health significance of various measures (e.g., how do you translate contaminant blood levels or changes in organ weight into health effects?)
- probabilistic estimates of exposure and risk
- estimates of both pre-control and post-control risk levels
- population and, where obtainable, sub-population exposure estimates
- potential effects and likelihood of occurrence
- timing of risks/latency period of risks.

Economic information of potential use to risk assessors:

- adverse effects for which economists have valuations
- description of population(s) that might be exposed to the hazard
- chemical uses and use patterns that might provide insight into potential exposures
- information on potential risk management alternatives (e.g., substitutes analysis)
- identification and quantification of trade-offs of the various control options.

Risk assessment uses information that may not always be included in the final risk characterization. A lot of richness in information may be lost in the transition from risk assessment to economic analysis, especially in animal and epidemiological data. Some expressed a need to incorporate non-numerical data into economic analysis. Risk assessors and economists should explore which additional information can be retained from risk assessments and how to communicate that to economists. Consideration can be given to capture environmentally relevant information by presenting the quantities of environmental effects in the relevant biophysical units separately and distinctly from any associated monetary values of these effects.

When Should Coordination Begin?

Coordination and integration of risk assessment and economic analysis must begin at the outset of the process before either assessment is initiated, and must continue throughout. Generally, inclusion of risk and economic information in risk management should not be a linear, sequential process. More often these analyses should be performed in parallel. Risk managers also play a role in the coordination of the disciplines.

Estimating Effects When Dose-Response Relationships Are Not Well-Defined

Economic analyses need information about risks expressed as probabilities. In many cases, risks are not expressed as probabilities, especially for effects other than cancer. Sometimes, dose-response data are not available or the degree of confidence in low-dose extrapolations is very low. Uncertainties should be articulated in both risk assessment and economic analysis.

Some attempts have been made to quantify noncancer risk in terms of probability. One example is found in Nakanishi (2000)[6] where the probability of immunological effects for fetuses from exposure to dioxin-like compounds was estimated although a dose-response function was not used.

Toxicological studies are not necessarily designed to provide information useful for low-dose extrapolation. Better coordination between risk assessors and economists might encourage research that will better characterize relevant dose-response relationships, especially in the low-dose range.

Other Observations:

Cost-benefit analysis may be very difficult in certain cases. Monetization of benefits may not always be possible. Other approaches to comparing risk management alternatives should be considered where appropriate. Approaches for comparing risk reduction across alternatives that do not monetize benefits include Loss of Life Expectancy or Quality of Life. While these methods do not provide insight into the efficiency of an alternative, they should be considered as alternatives to monetization in some cases.

Cost-benefit and other economic analyses should be implemented at the outset of a project, concurrent with risk assessments, so that a dialogue between economists and risk assessors can take place. Doing so will allow the relevant data and information for the cost-benefit analysis to be generated and will position the cost-benefit analysis as an input into the decision, thus reducing perceived or actual instances of justifying of a decision already made.

[6]Nakanishi, J. (2000). "What have we achieved: an introduction to a case study on dioxin", *Proceedings of the 3rd International Workshop on Risk Evaluation and Management of Chemicals.*

Cost-benefit analysis should not be the sole factor used to make risk management decisions. Decision analysis approaches, such as multiple criteria analysis, may provide useful guidance for including cost-benefit analysis and other information in decision-making.

Economic analyses should characterize the confidence placed on economic data derived from risk assessments. Uncertainties in risk assessments, such as the level of confidence in a database or in a distribution, need to be stated clearly. Some participants felt that most of the uncertainty in an environmental economic assessment resides in the risk assessment and the estimates of environmental effects and consequences, not in the economic data.

Topic II - Issues of Evaluation Processes and Models

In order to promote successful integration of risk and socio-economic information for the purpose of risk management, this session focused on areas where risk and economic modeling assumptions may traditionally differ and explored how those assumptions affect the information developed by the two disciplines. Participants discussed alternative assumptions or approaches that may be appropriate when developing integrated information.

Use of Judgment

Risk assessment generally requires judgments to be made about dose-response relationships outside of the range of doses administered, e.g., extrapolating low-dose effects from high-dose data). Workshop participants noted that it is particularly difficult to obtain accurate data at low-dose ranges or where risks are small. Concern was expressed that such judgments may be hindered by the use of uncertainty factors. It is unclear whether inferences made from either risk assessment or economic analysis are consistently made by those most qualified to do so, be they the risk assessor, the economist, or the policy-maker.

Uncertainties

Types and degrees of uncertainties differ in risk assessment and economic analysis, making characterization and communication of uncertainties important. Uncertainties result from multiple unknowns or assumptions in either type of analysis. In addition, uncertainties may be compounded in the economic analysis because of the uncertainties in the input from the risk assessment. Uncertainty includes both novel and unknown outcomes and both types of uncertainties should be explained to decision-makers. For example, the uncertainty associated with estimates of willingness to pay should be explained to risk assessors and to policy-makers.

The nature and extent of uncertainties, unintended consequences, key assumptions and areas of judgment, including value judgments, may be delineated by either the risk assessor or economic

analyst. Because of the possible interrelationship between uncertainties in risk assessment and economic analysis, characterization of uncertainties will benefit from increased collaboration between the two disciplines.

Uncertainty can be handled several ways. It can be ignored, probabilities can be presented, or conservatism can be applied. Use of ranges was considered a helpful approach for communicating uncertainty, as were high, medium, and low probability designations. Risk assessors and economists approach conservatism differently. Risk assessment methods build in conservative factors and assumptions that exaggerate risk, while economists use conservative factors and assumptions that tend to overestimate costs and underestimate benefits.

Some indicated that it should be accepted that uncertainties will always exist and that the process of risk management needs to remain open for future iterations based on acquiring new information.

Alternatives to Monetization

Certain types of costs and benefits can be difficult to monetize and methods used are often contentious. This problem can be particularly difficult in the evaluation of true ecological costs and benefits. It was suggested by some that alternative approaches for valuing or otherwise describing benefits should be developed along with continued development of valuation approaches. Others indicated that this is likely misguided as a number of studies have been done although not published in the mainstream economic journals. For example, Donald McAllister (Evaluation in Environmental Planning - Assessing Environmental, Social Economic and Political Trade-Offs, 1980) compares weighting techniques used by economists (monetary values), landscape planners, environmental risk assessors, and social psychologists. In addition, Great Lakes studies of the late 1980's were also mentioned.

Integration Issues

Examples from other professional areas may serve as models of ways that information can be used and how coordination can be achieved. Discussion indicated that risk assessors and economists have worked closely together, for example, in the field of civil engineering. To enhance integration, it should be made clear that economic analysis does not direct risk assessment.

The term "integration" should not be construed to mean that socio-economic analysis outputs would have any influence on the essential outcome of the scientific content of the risk assessment. Rather "integration" in this context relates more to the manner of analysis and presentation of risk assessment results such that these results are tailored to the extent possible to inform socio-economic analysts and thereby improve decision-making in risk management. The

fundamentals of risk assessment need to be clearly specified, transparent, and independent of socio-economic analysis.

Further discussions require increased emphasis on and more clarity in the definitions of risk management, risk characterization, risk assessment, and economic analysis and their applicability within implementation planning. This is needed to assure that there is no confusion between the functions carried out in each discipline and the people undertaking these functions. There is recognized opportunity for further discussion of the role of assigning value to a particular effect, species, etc. and the need to determine and consider those values while conducting scientific and economic analyses. Risk managers must understand and address the specific value assumptions implicit in the information development process which feeds the risk management decision.

Other Issues and Observations

Risk assessors and economists should consider trying to make better use of existing exposure data and, where gaps exist, more data should be collected.

The factors evaluated in both the risk assessment and economic analysis should be meaningful to the public and described in terms that can be understood by the general public. Often, numbers produced in an economic analysis take on a "life of their own" and the public may be uninterested in the details or the uncertainties of the analysis. Analysts should be diligent in conveying the limitations and applicability of the information.

It was noted that risk managers often have ethical considerations when making decisions. Cost-benefit analysis, per se, does not address ethics as it does not address the distribution of costs or benefits. However, other economic analyses can offer insight into how costs and benefits of a risk management action are distributed, and these, too, can be improved by many of the recommendations of the Workshop.

It was also noted that the information developed in cost-benefit analyses is just one of many factors considered by the risk manager in the decision making process. Often risk assessment and economic analyses are of little consequence in a decision where a political mandate is paramount.

Topic III - Broadening the Assessment Approach

Economic analysis constructs a story for decision-makers about what can be expected to happen if a risk management alternative is implemented (e.g., what the costs and benefits are likely to be, how they might be distributed, etc.). Decision-makers should be given the most complete and comprehensive picture possible of what the likely effects of a risk management action might be.

Risk and socio-economic analyses can be used to examine an array of possible consequences of risk management alternatives and their various impacts on resource allocation and risk. Integrated

risk and socio-economic analyses are envisioned to coincide as much as possible on toxicity endpoints, and assumptions, in order to provide more comprehensive information to the risk manager.

Qualitative and Quantitative Information.

It is generally agreed that quantitative information is preferable to qualitative information for purposes of analysis and review; however, quantification is not an end unto itself. Some participants expressed that quantification should not be performed or should be carefully considered when confidence in the underlying data is low. Often, professional judgment can be used instead and is considered by some to be "better than nothing." For example, concluding that acute health effects are likely to be significant but cannot be quantified is probably better than saying nothing about expected effects, assuming that supporting information is available. Others expressed that quantification may still be undertaken even with low confidence in the underlying data as one would still be able to gain knowledge and insight by systematic evaluation. In any event, applying highly uncertain data in a cost-benefit framework may be expected to stimulate the development of more certain data or information.

Because risk assessment and economic analysis are used to describe what will occur if risks are managed, qualitative information is often useful. Therefore, decision-makers should be provided with both quantitative (including monetized and non-monetized) and qualitative information. Including qualitative information highlights the importance of communicating judgments, uncertainties, and assumptions should be clearly articulated for the decision-maker. Care in presentation is important because numbers and distributions imply a degree of certainty that may not exist. People tend to attach great significance to numbers and may not read or understand qualifiers as they should. Explaining how data are derived (assumptions, etc.), in addition to articulating judgments and uncertainties, may also clarify why particular information elements should be meaningful to the decision-maker or the public.

Participants noted a difference between truly quantitative information and information that has been subjected to quantitative analysis. For some, the valuation of having fish in a lake is not quantitative information in the same sense that counting (estimating based on sampling results) the number of fish in the lake would be quantitative or numerically based.

Decisions about the degree to which quantification should be pursued are situation-dependent. Important to such decisions is the value that the information will provide to the risk manager compared with the cost of developing it, the costs of making a poor decision, the importance of the data to the decision, and other factors. For example, in a case where the costs of a risk management action are low and a qualitative assessment of risks and benefits shows great advantages to managing the risk, it may not be necessary to provide quantitative information on risk reduction and benefits in order to make the risk management decision. Conversely, risk management actions that are likely to have significant economic impacts may justify investing in better data to support the decision. Limitations in data and information should be acknowledged.

There are many approaches for incorporating qualitative information into quantitative analyses that are common to both risk assessment and economic analysis, such as the use of expert input and expert judgment. As with any other use of judgment in developing analysis, it remains important to explicitly document assumptions, uncertainties, lines of evidence, value judgments, etc. Other approaches that use qualitative information can include "what-if" scenario analyses, lexicographic techniques, and dominance ranking. There may be some advantage to involving experts in other disciplines (sociologists, anthropologists, ecologists, etc.) when incorporating unquantified information.

Some participants considered monetization to be one consideration, but not the major one, in risk management decision-making. This is consistent with the thinking that quantitative information is preferable to qualitative information for the purposes of analysis, but that it is not preferable in a more general sense. While quantitative information may be easier to analyze and otherwise manipulate, it is not necessarily the most relevant or useful. In addition, it was noted that assessments based only on monetized or monetizable endpoints may lead to biased conclusions.

Substitution

Often, a chemical risk management action, expected to affect a chemical's use, distribution, and manufacture of chemicals and processes, will result in the introduction of a substitute chemical or manufacturing process. Part of the information provided to a risk manager should include the risk, benefit, and cost information associated with that substitution. Deciding which substitute (e.g., chemicals and/or processes) to analyze may be challenging because there may be a wide variety of substitutes available. A substitution bias often exists as a function of the information available. Because information on a substitute chemical and/or process may be limited, conservative analyses may bias analytical results, underestimating the risks and costs while overestimating the benefits associated with the substitute.

The goal of substitution analysis is to provide a similar level of analysis for the substitution chemical or process as has been provided for the chemical considered for risk management. Resources and information may preclude this. Selection of substitutes and relevant toxicity endpoints can be aided by several pieces of information. Economic analysis of markets, and possibly of processes, can help to identify specific substitution alternatives. Consideration of the hazards and exposures associated with specific chemicals and/or processes may assist in narrowing analyses to the most relevant health or environmental effects. Economic analysis or use patterns and other information can be useful in identifying possible exposure pathways and populations. Therefore, increased coordination between risk assessors and economists will aid in the selection of substitute chemicals or processes for evaluation.

Selection of Adverse Health Effect Endpoints

Selection of appropriate effects to examine when evaluating the impacts of either a chemical of concern or its potential substitutes can be influenced by the hazard and exposure data that are available. For economic analysis, all endpoints may be of interest, whether they are the primary effect of concern or not. It is generally assumed that reducing the risk of most concern will also reduce other risks, but this is not always the case and should be thoughtfully considered. Expected effects on environment or human health must be clearly described and meaningful to the public. Often, an economic assessment will attempt to understand and present which effects are of greatest value or concern to the public.

Comparing Unlike Effects

It is difficult to rank degrees of adversity; severity of effects is more manageable. Economists use people's preferences as a basis for comparison. Toxicology studies sometimes look for structural or functional changes (e.g., liver enzyme changes), not disease states. People may not be aware of the clinical consequences of an initial symptom or indicator, for example, whether a 10% reduction in lung function impairs health.

To use economics to compare dissimilar effects, "silver threads" are needed that tie the risk assessment to the economic analysis and help guide the economist. Because there may be a plethora of dose-response data for some highly studied chemicals, there is a potential for "double counting" or over-emphasizing some effects if there is poor communication between the risk assessor and economist.

Timeliness of Collaborative Efforts

Collaboration between risk assessors and economists can only be effective and useful if the effort does not unduly slow the risk management process. To prevent delays from occurring, several suggestions were considered, including movement away from a sequential risk management process to one incorporating iterations, conducting concurrent risk and economic assessments, iterations, and adaptive, continuous improvement approaches. Development of and reliance on general principles for coordination and integration of risk and economic information were also expected to be useful in this regard. Better problem formulation at the beginning of risk management decision-making, involving risk assessors, managers, and economists was also considered useful. Projects with elements common to both disciplines were suggested as a way to test whether and how to improve cooperative approaches.

Other Observations

Some breakout groups discussed the role of ethics in risk management and the importance of considering ethics in the risk decision making process. This was considered particularly relevant in "willingness to pay" quantification in relation to involuntary risks.

While increased collaboration among risk assessors and economists can improve the integration of the work of these disciplines and thereby may improve chemical risk management decision making, participants indicated that it should be acknowledged that analyses sometimes impose little influence on the decision making as political factors may dominate the process.

ANNEXES

Annex 1. PREWORK PROVIDED TO PARTICIPANTS PRIOR TO THE WORKSHOP

Workshop on
the Convergence of Risk Assessment and Socio-economic Analysis
to Better Inform Chemical Risk Management Decisions

Breakout Discussion Topics

The objective of this Workshop is to create and improve links between risk assessment and economic analysis in support of chemical risk management decision-making and examine possible solutions to issues of common interest. To accomplish this, participants will be assigned to one of four breakout groups based on discipline and affiliation. Each breakout group will examine a series of three topics aided by the discussion thought-starters provided herein. Please review and carefully consider these topic summaries and discussion questions prior to the Workshop. Perhaps exploring these ideas with others in your organization or work interactions would expand the breadth of contribution to the Workshop.

The development of risk and socio-economic information for chemical risk management purposes is an interrelated process that is iterative in nature. An initial piece of information needed to manage risks from chemicals of concern is the level and nature of risk associated with exposure to such chemicals. Information about markets and uses for chemicals may provide a view of exposure potential and chemical or processing alternatives. Once concerns about a potential risk have been identified, risk management alternatives may be considered. Some of the important implications of risk management actions can best be understood after evaluating changes in risks, costs, benefits, and other effects likely to result from various alternatives. Developing these types of information is the challenge that the risk assessment and economic participants will address in this Workshop. The following discussion topics help to identify barriers, opportunities, and next steps for collaboration as part of this process.

The first breakout topic offers participants an opportunity to explore the types of inputs and outputs developed by risk assessment and economic analysis and possible means by which outputs of risk assessment can support the success of economic analysis and vice versa. The second breakout topic provides an opportunity to discuss conflicts among modeling assumptions relied upon by each discipline and whether there are alternative approaches or assumptions that would promote successful integration for improved risk management decision making. The third discussion topic challenges participants to broaden their consideration of endpoints, options, and approaches to better inform chemical risk decisions.

Discussion leaders - one risk assessor and one economist for each breakout group - will guide their groups through discussions of barriers to integration and means to overcome them. Groups

will be asked to distinguish between recommendations that may be acted upon in the near term, those requiring more time, research, or substantial resources, or those that appear to be intractable. At the end of each session, the groups will report on their discussions. The Workshop will conclude with a plenary discussion of recommendations.

Topic I - Inputs and Outputs

While the information developed by each discipline may serve to answer different questions for the risk manager, risk assessments and socio-economic analyses can also integrate information to make predictions about the effects of risk reduction measures. Integrating risk and socio-economic information requires that each discipline provide inputs for the other that can serve to strengthen the information provided to the risk manager. This session explores the types of inputs used and outputs developed by the disciplines that can serve to support each other.

1) Both risk assessment and socio-economic analysis use a variety of types of information about exposure, toxicity, chemical or process substitution, and production. What information is developed in a risk assessment that is useful in socio-economic analysis and vice versa? Are there inputs and outputs to/from each that have the potential to be shared to improve analyses?

2) Economists evaluate benefits of risk-reducing actions using estimates of risks expressed as probabilities. Risk assessments often evaluate risk by comparing exposures to a reference standard, such as hazard quotients or by comparing actual exposures to exposures known to produce adverse effects ("margins of exposure"). Are there risk approaches that can estimate probabilities when dose-response relationships are not well defined? Can such nonprobabilistic risk evaluations be interpreted and used in a socio-economic analysis?

3) Are there other examples of issues where discussion of the integration of inputs and outputs could be beneficial?

Topic II - Issues of Evaluation Processes and Models

Approaches used by risk assessors and economists to model risks and socio-economic effects often rely on conflicting assumptions built. This session discusses areas where modeling assumptions may traditionally differ, explores how these differences can lead to conflicting analyses, and evaluates whether there are approaches or alternative assumptions that may be more appropriate or helpful when developing integrated information.

1) Quantitative socio-economic analyses provide estimates of benefits to society. To do so, they rely on population risk estimates. Useful expressions of risk reduction may be statistical lives saved (human health) or percent changes in population levels (ecological). In contrast, risk assessments frequently provide estimates of individual risks, for instance, to the individual most exposed. Can socio-economic analyses use individual risk estimates to provide useful estimates

of benefits to society? Can population risk estimates reasonably be developed as a complement to individual risk estimates?

2) Both risk assessments and socio-economic analyses are uncertain. How are uncertainties addressed by the respective analyses? How is uncertainty in chemical risk assessment captured in the socio-economic analysis? Does uncertainty in socio-economic analysis affect risk assessment? What suggestions are there regarding how uncertainty is handled when integrating risk and socio-economic analysis?

3) Because of uncertainty, socio-economic and risk analyses may take a conservative approach to be health-protective. The degree of conservatism, however, may differ between the two analyses. Chemical risk estimates may be designed to accommodate a margin of safety and use upper bound estimates in order to describe exposure levels that are protective. Socio-economic assessments attempt to provide best estimates of benefits (value of risk reduction) in order to compare them to the costs of achieving risk reduction. How can the differences in the degree to which these analyses are conservative be addressed? In addition to conservative estimates, can the risk assessments provide information on best estimates of risk for use in socio-economic analysis?

4) Socio-economic analysis of a risk management alternative compares "the world **with** the policy alternative" to the "world **without** the policy alternative" (the baseline scenario), with the effects of the option being the difference between the two. To estimate a baseline, an analysis must estimate how the economy will appear if no action is taken. This analysis can be expressed as a point estimate (e.g., consumption of a chemical is currently 1 million tonnes and will continue) or a trend (consumption is increasing at a rate of 10% per year and will continue). Estimates of risks without the policy option (baseline) and with the policy option are needed to assess the option's effects. The baseline for risks may also be estimated several ways. Ideally, integrated of risk and socio-economic analysis would rely on the same baselines (e.g., if consumption of a chemical is increasing over time, the risk assessment would reflect this). Can baseline selection be coordinated for the two analyses? How? What types of considerations are important to each discipline for setting the baseline and how are baselines generally viewed (e.g., trends, point estimates)?

5) Where data limitations exist, can surrogates be applied? If not, how can qualitative assessments be carried out? How can these be applied in decision making?

6) Are there additional process issues that can be improved by discussion of integration issues?

Topic III - Broadening the Assessment Approach

When risk management actions on chemicals are contemplated, economists examine the resource trade-offs of those actions and risk assessors examine the changes in levels of risk associated with those actions. Risk management actions are likely to result in varied effects on resource allocation and risk level. In order to fully serve the risk manager and the public, an array of effects of risk management alternatives can be examined by risk and socio-economic analyses. Such an array would include broad consideration of a variety of endpoints associated with human health and the environment. Integrated risk and socio-economic analyses could be expected to coincide on assumptions and the endpoints and chemicals they address so as to provide more comprehensive information to the risk manager. These analyses are likely to extend both the risk assessments and economic analyses to include consideration of more health and environmental endpoints, and thereby do a more thorough job of describing the implications of risk management actions under consideration.

1. Information from risk and socio-economic analyses can provide both quantitative and qualitative information. Quantification is generally preferred. How can analysts determine when quantification is inappropriate and causes an analysis to lose its usefulness? How can plausible scenarios and professional judgment be used to develop integrated risk and socio-economic information when data are unavailable or uncertain? When is some information so uncertain that it is preferable to not provide it at all? How should uncertainties in the analyses be presented to the risk manager?

2. A wide range of effects, both socio-economic and risk-related, could result from risk management alternatives. It is likely that developing information for all effects would not be possible, however, analysts will want to ensure that an appropriate amount of information has been developed to support a level of confidence appropriate to the impact of the decision. How should risk assessors and socio-economic analysts determine which options, e.g., which chemicals or process substitutions, should be analyzed? What factors should be considered by both disciplines and how should work be coordinated?

3. For substitution analysis (chemicals and/or processes), the information available on the substance or process under question may be more extensive or of a different nature than would likely be available on substitutes. For example, information on long term effects or technical performance for a new chemical may be unavailable or limited. How should analysts deal with this added uncertainty or lack of common baseline? What factors should be considered by both disciplines and how should work be coordinated?

4. Risk assessors attempt to measure the potential for adverse human or ecological effects from exposure to a given chemical; however, not all adverse effects or endpoints will be equal in magnitude or significance, e.g., cancer versus skin irritation. Economists measure both societal costs and benefits (value of risk reduction) of risk management measures. When comparing risk management measures, how can adverse effects to the environment or human health of differing severity adequately be compared? How should their costs be compared? How can differences in

magnitude or significance of adverse effects be reflected in the benefits analysis? What information could be presented and how?

5. Are there other issues related to broadening approaches to assessing risk and the socio-economic implications of risk management alternatives that can be improved through communication among risk assessors and economists?

Working Definitions of Risk Terms as They Relate to Chemical Risk Management

Adverse Effect:

A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to other challenges.

Assessment Endpoint:

The explicit expression of a value to be protected, such as human health or a fish population.

Critical toxicity value (CTV):

A quantitative expression (e.g., LC 50 (lethal concentration)) of toxic effect reflecting the dose required to produce a specified level of response. CTVs are used in risk characterization for the calculation of an estimated no-effects value (ENEV).

Damage:

The severity of injury or the physical, functional, or monetary loss that could result if control of a hazard is lost.

Dose-response:

Relationship between the magnitude of potential, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Endpoint:

Adverse effect that characterizes the results of a toxicity test (e.g., neurotoxicity, cancer). Used in combination with “assessment” to indicate the species, kind, or category of organism that is being considered for risk of harmful effects (population abundance, reproductive success, etc.).

Exposure-based measures:

The use of margin of exposures or hazard quotients to describe risk.

Hazard:

A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb.

Hazard Quotient:

Estimated exposure divided by a reference dose or concentration; if the ratio is less than one, adverse effects are considered unlikely.

Individual risk:

The risk to an individual rather than to a population.

LCx or ECx:

The concentration of a substance that is estimated to cause some toxic effect on x% of the test organisms. The duration of the exposure must be specified. LCx (lethal concentration x%) or ECx (effective concentration x%) describes quantal effects, lethal or sublethal.

LO(A)EL:

Lowest-observed(-adverse)-effect level. The lowest concentration or dose in a toxicity test (noncancer) that causes a statistically significant (adverse) effect in comparison to the controls.

Margin of Exposure:

The exposure producing a specified level of an adverse effect in animals or humans divided by the actual or estimated level of human exposure. Often confused with the term margin of safety.

MATC:

The maximum allowable toxicant concentration, generally presented as the range between the NOEL and LOEL or as the geometric mean of the two measures.

NO(A)EL:

No-observed(-adverse)-effect level. the highest concentration or dose in a toxicity test (noncancer) not causing a statistically significant (adverse) effect compared with the controls.

Population at risk:

A limited population that may be unique for a specific dose-effect relationship; the uniqueness may be with respect to susceptibility to an effect or with respect to the dose or exposure itself.

Population Risk

Distribution of individual risks in a population risk, for example, population cancer risk is the expected increased incidence of cancer (that is, the number of new cases each year) for all the people exposed to a pollutant.

Population dose (population exposure):

Distribution of individual doses in an exposed population.

Reference standard:

A term used to describe an estimate of exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Risk:

The probability of deleterious health or environmental effects. Refers to the likelihood of harm, including acute or chronic effects to human health, the environment, the economy or the quality of life under specified conditions. The potential for adverse effects. Encompasses three components: hazard, potency, and exposure.

Risk Analysis:

Comprises risk assessment, risk management, and risk communication.

Risk Assessment:

The process of organizing and analyzing information regarding the nature and extent of a risk and/or risks for an exposed individual, group, society, or ecosystem.

Risk Communication:

Engages both the communicator and the audience in listening and explaining information and opinions about the nature of risks and other topics that express concerns, opinions, or reactions to risk messages.

Risk Management:

The process of analyzing, selecting, implementing, and evaluating actions to reduce risk.

Upper Bound:

A plausible upper limit to the true value of a quantity. This is usually not a true statistical limit.

Sources:

Commission on Risk Assessment and Risk Management. Final Report, Vol 2. Risk Assessment and Risk Management in Regulatory Decision-Making. GPO #055-000-00567-1. Washington, DC (1997)

National Research Council. *Risk Assessment in the Federal Government: Managing the Process.* National Academy Press. Washington, DC (1983)

National Research Council. *Improving Risk Communication.*. National Academy Press. Washington, DC (1989)

National Research Council. *Science and Judgment in Risk Assessment*. National Academy Press. Washington, DC (1994)

Working Definitions of Economic Terms as They Apply to Chemical Risk Management

Appraisal:

The process of defining objectives, examining options, and weighing up the costs, benefits, risks, and uncertainties of a policy proposal before a decision is made.

Baseline:

Estimates of the future status of health, environmental, and economic conditions under the status quo risk management options . It can be represented by point estimates or trends. Also called "base case".

Bequest Value:

The value placed by people on the continued existence of an asset for the benefit of future generations.

Cost-Benefit Analysis (CBA):

A technique for comparing costs and benefits resulting from various actions. It is a decision-making aid that facilitates the comparison of the costs and benefits (expressed in money units if possible) resulting from a policy or action. The goal of CBA is to compare alternatives on the basis of economic efficiency. Though CBA treats costs and benefits in common conceptual terms (i.e., attempts to avoid judgmental procedures typical of environmental impact assessments or cost effectiveness analysis) it does not say anything about the incidence of costs and benefits between different groups or the allocation of costs and benefits over time.

Cost Effectiveness Analysis :

A technique that can be used to identify the least expensive way of achieving a given environmental quality target, or the way of achieving the greatest improvement in some environmental target for a given expenditure of resources. Usually expressed as dollars per unit of environmental and/or health attribute, i.e. $/life saved.

Economic Analysis:

Analysis based on economic principles or approach aimed at evaluating all of the effects of a policy or project. Such analysis can take place either within or without a framework. Economic analyses are also useful in the determination of possible conflicts between competing goals of a policy.

Economics :

The study of the allocation of limited resources among unlimited competing uses.

Efficiency:

The allocation of goods to their uses of highest relative value. With efficiency, no activity can be increased without cutting back on some other activity**.**

Environmental Externalities:

Externalities exist when the welfare of one party is affected by its own actions as well as actions under the control of another. They occur with goods that remain unpriced and thus are external to the market, or for which no market exists, and that affect the welfare of at least one individual. Because environmental quality is an unpriced good, changes made to it by one party that affect, but are not under the control of another party are environmental externalities. Externalities are negative when they impose a cost to one party (i.e. pollution). They can be positive when the action of one party benefits another party (i.e. improved water quality). Discrepancies between social and private costs (see below) lead to externalities and therefore affect the efficiency.

Existence Value:

The value placed by people on the continued existence of an asset even though they themselves do not expect to see or use them.

Net Present Value:

The sum of a stream of benefits less the sum of a stream of costs over the life of an asset/project, adjusted or discounted so that future values (e.g., cash inflows and outflows) are expressed in current values (e.g., today's prices).

Non-use Value:

Values which are not related to direct or indirect use of the environment (consists of existence and bequest values).

Opportunity Cost :

This is an economic concept (as opposed to a financial or accounting concept) that describes the opportunities foregone by taking a particular course of action. Because a policy action results in the use of resources- labor, materials, land, that could be used to produce other things that people value, the opportunity cost of using these resources in response to a policy action is measured by what is lost by not using resources in their best alternative use.

Option Value:

The value of the availability of the option of using an environmental or other asset (which is usually non-marketed) at some future date.

Private Costs:

Costs of some activity or output that are borne by the individual or producer. They are usually measured by the market price of the resources that the firm or individual uses).

Social Benefits:

The gain in welfare attributable to a change in risk management practices. This can include improvements in human health and environmental conditions.

Social Costs :

Costs of some activity or output which are borne by society as a whole, and which need not be restricted to the costs borne by the individual or firm carrying out that activity or producing that output. Social costs, therefore, consist of the opportunity costs of resources used, together with the value of any loss in welfare, or increase in costs, that the activity causes to any other individual or firm.

Socio-economic Impacts:

Any impacts upon society/the economy as a result of an event, such as price changes, welfare changes, employment, reduction in health and environmental impacts, etc.

Substitute :

A good that can replace another good in terms of its function or derived utility. In other words, it refers to a good that can be exchanged for one another since they have the same uses or yield the same satisfaction.

Total Economic Value:

The sum of use values (direct, indirect, and option) plus non-use values (bequest and existence).

Use Value:

The value of something for which there is no market provided by people's actual use of it. (i.e., fish in a river for fishing, pleasure derived from looking at a clean river).

Sources:

Bannock, Graham, R. E. Baxter, and Ray Rees. *The Penguin Dictionary of Economics.* 2nd edition, Penguin Books, Ltd., 1978.

Lipsey, Richard G., Douglas D. Purvis, Peter O. Steiner. *Microeconomics*. 6thedition, Harper & Row , NY, 1988.

Pindyck, Robert S., Daniel L. Rubinfeld. *Microeconomics.* 3rd edition, Prentice Hall, Englewood Cliff, NJ, 1994.

Tietenberg, Tom. *Environmental and Natural Resource Economics*. Scott, Foresman and Company, Glenwood, IL, 1984.

Http://www.damagevaluation.com

List of Additional References

Essential Prework

Use and Limitations of Economic Analysis in Regulatory Decision-Making: Linking Risk Assessment and Economic Analysis (pp99-101)
http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/html/v2epa5.htm#5g

Optional Prework -- *General Background*

President's Commission on Risk Assessment :

General Site - (Home Page)
http://www.riskworld.com/riskcommission/Default.html

Vol.1 title page: "Framework for Environmental Health Risk Management"
http://www.riskworld.com/Nreports/1997/risk-rpt/html/epajana.htm

Vol.1 Table of Contents
http://www.riskworld.com/Nreports/1997/risk-rpt/html/epajanc.htm

Vol.2 title page: "Risk Assessment and Risk Management in Regulatory Decision-Making"
http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/html/v2epaa.htm

Vol.2 Table of Contents
http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/html/v2epac.htm

Examining Options, Linking Risk and Economics
http://www.riskworld.com/Nreports/1997/risk-rpt/html/epajan4.htm

Background on Risk Assessment

President's Commission on Risk Assessment:

Uses and Limitations of Risk Assessment for Risk Management Decision-Making
http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/html/v2epa4a.htm

Understanding Risk Analysis - A Short Guide for Health, Safety & Env.Policy Making, Internet Edition, Edited by American Chemical Society and Resources for the Future http://www.rff.org/misc_docs/risk_book.pdf

Environment Canada, Priority Substances Assessment Program:

Guidance Manual - Environmental Assessments of Priority Substances under the Canadian Environmental Protection Act
http://www.ec.gc.ca/cceb1/eng/psl2manual_e.pdf - (glossary on page xiii).
Condensed version:
http://www.ec.gc.ca/cceb1/eng/psl2summary.htm

Health Canada, Priority Substances Assessment Program:
Human Health Risk Assessment for Priority Substances
http://www.hc-sc.gc.ca/ehp/ehd/catalogue/bch_pubs/approach.pdf

Background on Economic Analysis and Benefit Assessment

President's Commission on Risk Assessment, Uses and Limitations of Economic analysis in Regulatory Decision-Making
http://www.riskworld.com/Nreports/1997/risk-rpt/volume2/html/v2epa5.htm#5b

Resources for the Future, Cost Benefit Analysis and Regulatory Reform by Raymond Kopp, Alan Krupnick, and Michael Toman.
http://www.riskworld.com/Nreports/1996/risk_rpt/pdf/resorces.pdf

USEPA, Office of Ground Water and Drinking Water, "Health and Dose-Response Data Needs for Benefits Assessment", August 31, 1999, Final Draft - Sections 2 and 3. (See next page for a reproduction of these sections)

DRAFT

Benefits Assessment Background

Extracted from "Health and Dose-Response Data Needs for Benefits Assessment", Section 2
USEPA, Office of Ground Water and Drinking Water
August 31, 1999, Final Draft

Benefits assessments are required by the 1996 Amendments to the SDWA, which obliges regulators to compare the benefits and costs of achieving a proposed MCL or TT. Benefits assessments may also be required under several other statutes and executive orders, including: Executive Order 12866, Regulatory Planning and Review; the Unfunded Mandates Reform Act (UMRA); the Small Business Regulatory Enforcement Fairness Act (SBREFA); Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations*; and Executive Order 13045, *Protection of Children from Environmental Health and Safety Risks.*

This section provides an introduction to the benefits assessment process (Section 2.1) and the major economic concepts underlying the benefits assessment (Section 2.2). The section concludes with a table listing the general categories of data analysts need to conduct a benefits assessment. (A detailed discussion of the specific data needs from HECD follows in Section 3.) More detailed guidance on the specific economic benefits valuation methodologies is available from the draft *EPA Guidelines for Preparing Economic Analyses* and the draft *Assessing the Benefits of Drinking Water Regulations: A Guidance Manual.*

2.1 Steps in Conducting a Benefits Assessment

A benefits assessment usually consists of three major steps, including:

Step 1—Identification of health effects

> Identifying the types of human health effects that might be averted by reducing human exposure to the contaminant.

Step 2—Quantification of health effects

> Quantifying health effects under baseline conditions, and predicting the net change in health effects under the regulation.

Step 3—Monetization of health effects

> Attaching a dollar value to the reduction in incidence of the health effects.

The benefits assessor always attempts to complete all three steps of the benefits assessment, but this is often not possible for all health effects. As a result, some health effects may be monetized, others may only be quantified in terms of potential reductions in incidence, and yet others will only be addressed qualitatively. EPA considers both monetized and non-monetized benefits when assessing whether benefits of the proposed regulation justify the costs. This makes it necessary for the benefits assessors to be aware of all the health effects that could potentially be reduced by regulatory controls.

2.1.1 Identification of health effects

The identification of health effects entails a comprehensive assessment of information from epidemiologic studies, clinical studies, animal toxicity studies, and related studies on pharmacokinetics and mechanisms of actions. This information is usually provided by HECD in Drinking Water Criteria Documents. After reviewing these documents and any other possible sources, benefits assessors compile a list of all the potential health effects to be analyzed. They then identify which health effects can be quantified and which can only be qualitatively assessed.

2.1.2 Quantification of health effects

Once the health effects of the contaminant being regulated are identified, the next step in the benefits assessment is to quantify the change in incidence expected as a result of implementing the regulation. The ultimate goal of the benefits assessment is to estimate the number of cases of death, disease, or other health effects avoided on an annual basis. The health data used to calculate the number of cases avoided are usually provided by HECD. Benefits assessors go through a modeling exercise to estimate the reduction in human exposure to contaminants and the associated reduction in health effects exhibited. Whether this modeling exercise can be conducted depends on the availability of dose-response information in the criteria document. The ability of health scientists to provide dose-response information, however, depends on the quantity and quality of the scientific data relating particular contaminants to specific health effects.

2.1.3 Monetization of health effects

As noted in the previous section, if dose-response information is available, benefits assessors can estimate the expected reduction in the number of cases of health effects that will be associated with a drinking water regulation. In the monetization step, the benefits assessor estimates the monetary value associated with avoiding these cases. For each health effect, this is generally done by estimating a dollar value associated with avoiding one case and multiplying that value by the total number of cases estimated to be avoided. For example, a drinking water

regulation may effectively reduce the number of annual fatal bladder cancer cases by 100. In the monetization step, the economist will estimate the monetary value for avoidance of one fatal bladder cancer case and multiply this value by 100 to obtain the total monetary value of the expected reduction in cancer incidence. Section 2.2 briefly discusses the economic methods for estimating the monetary value of an avoided case of disease or death.

2.2 Economic Methods for Valuing Health Effects

Methods used to measure the monetary value of a case of disease or death avoided are based on the economic concept of willingness-to-pay (WTP). In the case of drinking water regulations and associated health benefits, WTP is defined as the maximum amount of money that an individual would be willing to pay for a reduction in health risks associated with an improvement in drinking water quality. Sometimes benefits assessors measure willingness-to-accept (WTA) instead of WTP. In the context of this document, WTA is defined as the least amount of money that an individual would accept to forgo the increase in health benefits associated with an improvement in drinking water quality. WTP takes as its reference point the absence of the improvement, whereas WTA takes the presence of the improvement as its reference point.

Several primary valuation methods are available to estimate WTP and WTA for a reduction in a health risk. Fatal health effects are valued differently than nonfatal health effects and therefore different methods are used for each. The most commonly used valuation methods relating to human health benefits include:

Fatal health effects

1. Contingent valuation method (CVM)
2. Wage-risk analysis

Nonfatal health effects

1. CVM
2. Cost-of-illness (COI)
3. Averting behavior

The method ultimately chosen to value a health effect will be dependent on the available data, time, and resources. When assessing the benefits of drinking water regulations, however, benefits assessors often use existing studies' estimates of WTP or WTA for a reduction in a health risk, rather than conducting primary research using the methods listed above. This approach, also called "benefit transfer," is undertaken because benefits assessors often lack the time and resources needed to conduct the primary research.

Benefit transfer is used by EPA for the monetization of fatal health effects. Mortality risk reductions from drinking water regulations are generally valued using the value of a statistical

life (VSL), which represents WTP for a small reduction in mortality risk for a population.[7] VSL estimates are derived using CVM or wage-risk analysis, but given that these studies can be very time-consuming and labor-intensive, EPA has historically obtained VSL estimates from existing studies. A VSL estimate is multiplied by the number of fatal cases avoided to derive an estimate of the monetized benefits of a regulatory action.

Benefit transfer techniques are also frequently used for non-fatal health effects, but some primary research can be conducted as well. Although original contingent valuation and averting behavior studies are usually not undertaken by EPA, COI studies are often conducted. Benefit transfer is sometimes preferred over COI studies because the COI approach underestimates WTP to avoid an illness. This is because COI does not account for all effects of the illness, such as pain and suffering, effects on care givers, and more. Like any method, however, benefit transfer also has drawbacks, so whether benefit transfer is used or a COI study is conducted is largely dependent on available data.

Each of the primary valuation methods referenced above is described briefly below:

Contingent Valuation Method (CVM)

CVM involves using surveys to elicit respondents' WTP for a hypothetical good. Such a survey typically consists of a description of the good or the changes in the good (or policy or "health state") being valued, the hypothetical method of payment, questions to elicit respondents' WTP for the good, and questions to collect demographic information. For example, individuals may be asked to state the maximum dollar amount that they would be willing to spend each year in additional water service charges for a drinking water quality program that would reduce the risk of cancer by a specific amount (e.g., from 1/100,000 to 1/1,000,000).

Wage-Risk Analysis

Wage-risk analysis is based on the observation that wage is a function of job characteristics, including the risk of death, injury, and illness. This approach is based on the idea that workers prefer jobs with lower risk of death and therefore WTA an increased risk of death can be valued by examining the additional compensation that workers demand for riskier jobs. While this approach is not directly applicable to valuing changes in drinking water quality, it is included here because estimates of the VSL are frequently based on this approach (in addition to CVM studies).

[7] The VSL can be calculated by summing the individual WTP (which can be derived using CVM or wage-risk analysis) for a given risk reduction across a population. For example, if each individual in a population of 100,000 is willing to pay $10 for a risk reduction of 1/100,000, then the VSL would equal $1 million (100,000 * $10). This does not mean that an individual life is worth $1 million but rather, that the total value of reducing the risk for individuals in a population by a small amount is worth $1 million.

Cost-of-Illness (COI)

The COI method directly measures values using observed expenditures. It relies on measures of the costs incurred as a result of illness, including direct costs such as medical expenses, and indirect costs such as earnings lost while ill. To the extent that a drinking water regulation decreases the incidence of illness, these types of costs can be avoided; this means they provide an indication of the value of related benefits.

Averting Behavior

The averting behavior approach is based on cost of actions taken to avert potential health effects that result from exposure (e.g., consumption of contaminated drinking water). Averting behaviors include reduction in drinking water consumption, substitution of other sources of drinking water, and household treatment of drinking water. Households exhibiting these behaviors incur both explicit and implicit costs that translate into losses that could be avoided if higher-quality drinking water were provided. Explicit costs include direct monetary expenditures, such as the purchase of bottled water or filtration systems, while implicit costs include the value of time associated with undertaking averting activities (e.g., the time it takes to drive to the store or install the filtration system). The averting behavior approach can be used to generate a lower bound on the value of a reduction in a health risk. To generate this lower bound, averting expenditures often summed together with other components to measure the value of a reduction in health risk, such as lost time and the value associated with pain and suffering.

2.3 Data Needed for Benefits Assessment

Different types of data are needed for each step in the benefits assessment. Table 2-1 lists these general categories of data and identifies which group at EPA is responsible for providing the data, for both fatal and nonfatal health effects. Historically, HECD has classified health outcomes as either cancer or noncancer health effects. For the purposes of benefits assessment, however, health effects are better classified in terms of fatal or nonfatal health effects, because the monetization method used for the third step of the benefits assessment varies based on whether the health endpoint is death.

Regardless of whether the health effect is fatal or nonfatal, however, the data requirements from HECD are generally the same. Therefore, HECD should provide the same type of data for each health effect, regardless of whether the final outcome is death. As shown in Table 2-1, benefits assessors rely on HECD to provide the following data:

1. identification of potential human health effects
2. dose-response information
3. drinking water consumption information
4. relative source contribution factor
5. probability of death
6. description of the nature of the disease or other health effect

The remaining data listed in Table 2-1 are provided by the benefits assessors or the Office of Ground Water and Drinking Water (OGWDW) of EPA. Section 3 addresses in detail the specific data elements needed from HECD for each category listed above.

Table 2-1
Health Benefits Assessment Data Needs

Data Needed	**EPA Source**
Fatal Health Effects	
Identification of potential human health effects for each contaminant	HECD
Quantification of health effects for each contaminant	
Dose-response information for each health endpoint	HECD
Drinking water consumption information	HECD
Relative source contribution factor	HECD
Exposure information (e.g., contaminant concentrations, populations exposed)	OGWDW
Number of averted cases for each health endpoint	Benefits assessors
Probability of death	HECD
Monetization of reduced health effect for each contaminant	
Description of the nature of the disease or other health effect	HECD
Value of a statistical life	Benefits assessors
Nonfatal Health Effects	
Identification of potential human health effects for each contaminant	HECD
Quantification of health effects for each contaminant	
Dose-response information for each health endpoint	HECD
Drinking water consumption information	HECD
Relative source contribution factor	HECD
Exposure information (e.g., contaminant concentrations, populations exposed)	OGWDW
Number of averted cases for each health endpoint	Benefits assessors
Monetization of reduced health effect for each contaminant	
Description of the nature of the disease or other health effect	HECD
Description of treatment for the disease or other health effect	Benefits assessors
WTP value to avoid, or costs associated with, a disease or other health effect, or averting behavior costs and effectiveness	Benefits assessors
Additional information on averting behavior	Benefits assessors

DRAFT

Health-Related Data Needed For Benefits Assessment

Extracted from "Health and Dose-Response Data Needs for Benefits Assessment", Section 3
USEPA, Office of Ground Water and Drinking Water
August 31, 1999, Final Draft

3.1 Introduction

As noted in Section 2.3, ideally, benefits assessors would like health scientists to provide them with the following data for each health effect:

1. identification of potential human health effects
2. dose-response information
3. drinking water consumption information
4. the relative source contribution factor
5. probability of death
6. description of the nature of the disease or other health effect

This is somewhat of a "wish list," as it is recognized that the availability of these elements is highly dependent on the existing health effects data for a particular contaminant. Nonetheless, the benefits assessor needs to be provided with as much data as possible. For example, even if dose-response information is not available for a particular contaminant, it would still be useful to provide information from key scientific studies that show an elevated risk for a disease resulting from exposure to a contaminant—such data could at least allow benefits assessors to qualitatively address possible benefits.

This section describes, in further detail, the data needed from HECD as listed above. To illustrate why benefits assessors need more data than are currently provided, Section 3.2 discusses some of the difficulties that benefits assessors have had working with the data currently provided in the criteria document. Section 3.3 describes the specific data ideally needed from HECD in further detail. Section 3.4 concludes with a summary of the data needs. Section 4 addresses how the data should be presented.

3.2 Data Currently Provided

Traditionally, benefits assessors have obtained most of the health data they used from Drinking Water Criteria Documents. The criteria documents describe the cancer and noncancer effects that are potentially associated with a specific contaminant, based on a review of the available literature. Human data are presented, when available, as well as data from studies of animal species. The criteria documents also quantify some of the toxicologic effects.

The data provided in the criteria document for a contaminant can be used in the first two steps of the benefits assessment (identifying and quantifying health effects). The review of the available literature provides the necessary data to conduct Step 1 of the benefits assessment, identifying possible health effects. The utility of the criteria document's data for quantifying health effects (Step 2), however, may vary. For example, the data currently provided for quantification of noncancer health effects are sometimes difficult to apply in quantifying the number of cases of diseases or other health effects avoided. Also, there frequently is not enough information provided to separate fatal effects from nonfatal effects.

In the criteria documents, HECD quantifies health effects using the Reference Dose (RfD) for noncancer health effects and risk levels for cancer health effects. The traditional procedure used to derive RfDs for non carcinogens is referred to as the No Observed Adverse Effect Level (NOAEL) approach. The NOAEL is the highest experimental dose at which there is no biologically or statistically significant increase in the frequency of severity of health effects in the exposed group when compared to the appropriate control group. EPA bases the RfD on the dose of a contaminant associated with the highest NOAEL value, lower than the Lowest Observed Effect Level (LOAEL), among all of the adverse effects studied. When adverse effects are observed at all doses, then a LOAEL is used to determine the RfD.

From a benefit assessor's point of view, one of the major limitations of the NOAEL approach to deriving a RfD is that it only addresses a single health effect, called the "critical effect", the most sensitive health endpoint, and gives no information on the other health effects that could be associated with a contaminant. Also, the critical effect, such as a change in enzyme level or organ weight, can often be difficult to interpret in terms of a disease state. This limits the ability of the benefits assessor to account for all measurable improvements in human health. Another limitation of the NOAEL approach to deriving a RfD is that the resulting data cannot be translated into a number of cases of disease or other health effect avoided. Since consideration of dose-response relationships is very limited when deriving the RfD in this way, it is difficult to estimate the disease response for a given level of exposure to a contaminant. Given that benefits assessors need information on disease response to estimate the number of cases of disease avoided as a result of a drinking water regulation, use of the RfD is problematic.

The risk estimate for cancer provided in the criteria document is generally provided as a linear risk estimate (e.g., 1.7E-07 lifetime unit risk per µg/L). Benefits assessors translate this risk to an annual unit risk estimate by dividing the lifetime risk by 70 (based on a standard assumption of 70 years per lifetime). The annual risk estimate can then be used to estimate the number of cancer cases avoided annually due to a reduction in exposure to a contaminant, as needed for Step 2 of the benefits assessment.

The criteria document also includes information on standard drinking water consumption rate assumptions, such as 2 liters per day for an adult and 1 liter per day for a child. A relative source contribution factor (RSC) is also provided, which accounts for the percent of total exposure to a contaminant attributable to drinking water intake as opposed to other sources.

The criteria document also provides some information on the nature of the health effects resulting from exposure to a contaminant, but is limited in scope on this topic. Sometimes information on the severity of symptoms, duration of disease, or latency periods may be provided for a given outcome, but it does not generally detail a range of outcomes or the probability of death associated with each outcome.

Thus the information provided in the criteria document only supplies a portion of the data needed to conduct a benefits assessment. The most important piece of information that is needed, in addition to what is currently provided, is dose-response information for all adverse effects associated with carcinogens and non carcinogens. More detail on the nature of the health effects resulting from exposure to a contaminant would also be helpful to benefits assessors. The data needed from HECD for benefits assessment are described in detail in the next section. The section discusses current data provided, as well as additional data needed, to give a complete picture of all the data elements HECD should provide, if available, to benefits assessors.

3.3 Data Needed from HECD

Identification of Human Health Effects

To begin a benefits assessment, assessors need to identify possible benefit categories; for this, they need HECD to provide a list of all potential human health effects associated with exposure to the regulated contaminant. In addition, for each potential human health effect identified, HECD should cite the key studies linking exposure to the contaminant to that effect and whether the study is based on animal or human data. The most important health effects will be those for which there is the greatest amount of evidence in the literature linking contaminant exposure to the health effect.

In addition, it would be helpful if HECD could provide a general conclusion about the findings of the studies for each health effect, assessing the weight-of-evidence with which the contaminant has been linked with the health effect. If available in the literature, data on any sub-populations that exhibit a greater risk of the health effect should also be provided. For example, it would be helpful to know whether any age groups have a higher risk of developing a particular condition or are more likely to die from a disease. If key studies for a human health effect are based on health effects observed in animals, a summary of the possible human health effects should be provided, as well as a qualitative commentary addressing the link between the animal and human health effects.

Dose-Response Assessment

For each of the human health effects identified, the benefits assessor needs information on dose-response relationships that can be used to estimate the risk of developing a disease or condition. Given that the baseline and post-regulation contaminant concentrations are likely to be in the range of low dose levels, it is especially important that data on dose-response relationships at low dose levels are included in the information provided. The benefits assessor would prefer to

obtain dose-response information for all human health effects identified, to the extent supported by the data. If substantial data are available and presenting all of them would be too much effort, HECD should consult with the benefits assessor to determine which health effects would be most useful from an economic standpoint. Ultimately, the benefits assessor is interested in being able to determine the annual probability of developing a disease or condition at the baseline and post-regulatory concentrations of the contaminant in the drinking water, for each potential human health effect. The benefits assessor will then use this dose-response data, together with information on exposure (including data on drinking water consumption provided by HECD), to estimate the number of cases of each health effect avoided as a result of the drinking water regulation.

Ideally, dose-response assessments for health effects would be provided as lifetime unit risk estimates or as nonlinear dose-response functions. Dose-response assessments should be provided for every health effect identified, if possible. Any information that would help understand how the dose-response estimates were derived is also helpful to the benefits assessor (e.g., whether the effect associated with each dose is an annual or lifetime probability). Similarly, if possible, dose-response assessments should be made for more sensitive sub-populations as well, although it is recognized that the data required to do so are often not available.

As discussed in Section 3.2, the dose-response data currently provided for cancer effects can be used by benefits assessors to estimate the number of cancer cases avoided. The type of quantitative data provided for noncancer effects (e.g., RfD), however, cannot be readily used for benefits assessment. The traditional approach to estimating a RfD (based on a NOAEL or LOAEL) is actually not particularly helpful in quantifying noncancer health effects. For example, although it might be possible to quantify benefits to some extent by determining the number of people exposed to contaminant levels above the RfD, this cannot be translated into a number of cases of a health effect avoided. To develop such an estimate, one would want the dose-response information about the health effect on which the RfD is based. Such information would be helpful to at least quantify the number of cases avoided for that health effect.

An alternative approach to the traditional methodology for estimating an RfD, as proposed in the EPA's Risk Assessment Forum's *Use of the Benchmark Dose Approach in Health Risk Assessment* (EPA, 1995), is the Benchmark Dose Approach (BMD). The BMD is defined as a statistical lower confidence limit on the dose producing a predetermined level of change in response relative to controls. The predetermined level of change is designated as the benchmark response (BMR, which is set equal to a chosen percentage increase in the incidence of an effect (e.g., 1 or 5 percent). The first step in calculating the BMD is deriving a statistical dose-response curve and its corresponding curve of confidence limits. The BMD is then determined by selecting a point on the lower confidence dose curve for a specific BMR. The advantages of the BMD approach over the traditional methodology for deriving an RfD is that it considers dose-response relationships to a much greater extent. Furthermore, the BMD approach is not limited to modeling a single health effect to derive the RfD and may even provide dose-response information for multiple health effects. It might also be possible to use the BMD data with the baseline and post-regulation concentrations of the contaminant to determine the health

effects at those concentrations. This approach would require benefits assessors to provide baseline and post-regulation concentrations of the drinking water contaminant to HECD and therefore would most likely occur after publication of the criteria document. Use of the BMD approach in developing RfDs, therefore, looks promising in terms of the ability of benefits assessors to quantify noncancer health benefits in the future.

In the past, HECD has provided benefits assessors with a range of the expected number of cases (e.g., 0 to 10,000 cases of bronchitis avoided) for certain noncancer illnesses, such as those related to microbial contaminants, independently of the information provided in the criteria document. These estimates are difficult for the benefits assessors to work with because the range is often very large, making it difficult to choose a reasonable range to be represented. If this is the only information that is available, it would be helpful if HECD could provide additional information to more narrowly bound the estimates (e.g., it is most likely that exposure will result in 100 to 200 cases).

Temporal distribution of the risk would also be useful to the benefits assessor, although temporal data is traditionally not provided by HECD. When available, however, it should be provided because this information could be used to characterize any major changes in risk over long periods of exposure. Ideally, benefits assessors would like a distribution of risk based on cumulative exposure, as well as an age distribution of risk. In the absence of such data however, a qualitative assessment of these issues would be useful as well.

Drinking Water Consumption Information

The benefits assessor also needs information on drinking water consumption. As indicated earlier, standard drinking water rate assumptions are traditionally provided in the criteria document (e.g., 2 liters per day for an adult). Any other drinking water consumption information used to derive the MCLG should be provided whenever possible, such as data on drinking water exposure frequency (e.g., 365 days per year) and duration of exposure (e.g., 70 years). In addition to providing drinking water consumption information for the general population, it should also be provided for sub-populations whose consumption pattern may be different (e.g., children or people with some chronic illnesses), when available.

Relative Source Contribution Factor

The RSC factor HECD provides is useful and should continue to be provided. The RSC crosses all chemicals and includes information on the proportion of total exposure to a contaminant from water as opposed to other sources. Volatility of the contaminant and the temperature of the water can affect the RSC, in some cases.

Probability of Death

Once the number of cases of each health effect avoided has been calculated, the benefits assessor needs to separate the cases into fatal and nonfatal health effects. To do this, data on mortality rates are needed. HECD has not traditionally provided mortality rates for health effects, and benefits assessors have obtained this information from other sources. However, if this

information is available to HECD, it should be provided. Any additional information on factors influencing the mortality rate, such as changes in risk of death with age, would be useful as well.

Nature of the Disease or Other Health Effect

The benefits assessor also needs data to characterize the nature of the disease associated with exposure to the contaminant. These data include information on:

1. the type of symptoms of the disease or other health effect (e.g., persistent cough, abdominal pain)
2. duration of the disease or other health effect (e.g., chronic or acute)
3. severity of the disease or other health effect (i.e., degree to which an individual's activity is impaired)
4. the latency period between exposure and the onset of the illness

This information is sometimes used in the monetization step of a benefits assessment to determine the cost of medical treatment and lost productivity associated with disease or to assess whether a CVM estimate from the literature could be used as part of a benefit transfer exercise. It is recognized that the toxicologic and epidemiologic studies HECD reviews tend to count (rather than describe) health outcomes, and therefore information on the nature of a disease or other health effect may be limited. However, a given outcome in a study may be described in terms of severity of symptoms, disease duration, and latency, and the benefits assessor would be interested in obtaining this type of information, if available. The benefits assessor investigates the treatment regime and recovery period associated with the disease or other health effect as part of the monetization step of the benefits assessment.

3.4 Summary of Data Requirements

To simplify HECD's task of providing health-related data to benefits assessors, a quick-reference summary table of the data needs has been included (Table 3-1 below). The table summarizes all the information in Section 3.3 and is meant to serve as a guide to the type of data that benefits assessors need. However, any additional data that could possibly be useful should be provided. Communication between HECD and the benefits assessor during the benefits assessment process is also recommended, especially in cases where large data sets exist. This will help ensure that information most relevant to the benefits assessment is provided, and should help to minimize HECD's level of effort in providing the data.

Table 3-1
Quick Reference Summary Table of Health Data Needs

	Type of data required for each health effect	Further interpretation/examples
For Step 1 of the benefits assessment: identification of health effects		
	List key studies for health effects	Health effects listed should include those for which there is the greatest amount of evidence in the literature linking contaminant exposure to the health effect. Then, for each human health effect identified, HECD should cite the key studies linking exposure to the contaminant to that effect and whether the study is based on animal or human data.
	Information on the weight-of-evidence with which data have been linked to the health effect	A general conclusion should be drawn about the literature's evidence regarding the link between the health effect and exposure to the contaminant.
	Any information on sub-populations that experience an increased risk of the health effect	For example, children might be more susceptible to leukemia caused by a drinking water contaminant.
For Step 2 of the benefits assessment: quantification of health effects		
	Dose-response assessment	Provide any assumptions made during the dose-response assessment. If a range of cases is provided for dosages (e.g., 0 to 10,000 cases), provide additional information on the most likely events (e.g., 100 to 200 cases). Also, provide a dose-response assessment for any sensitive sub-populations.
	Temporal distribution of risk	For example, the age distribution of risk, distribution of risk based on cumulative exposure, or a qualitative assessment of how the risk changes over time.
	Drinking water consumption data	For example, 2 liters of water per day, every day for 70 years.
	Relative source contribution factor	For example, the RSC could be 100 percent if drinking water is the only source of exposure.
	Mortality rate	Should be provided as a percentage probability. Provide different rates for sensitive sub-populations.
For Step 3 of the benefits assessment: monetization of cases of disease, or other health effects, avoided		
	Type of symptoms	For example, persistent cough or abdominal pain.
	Duration of disease	For example, chronic or acute or length of disease.
	Severity of disease	Provide the degree to which an individual's activity is impaired.
	Latency period after exposure	For example, 2 years before the onset of symptoms.

Annex 2. Participants List

Linda Abbott
Office of Risk Assessment and Cost-Benefit Analysis
US Department of Agriculture
Stop 3811, Room 5248 S
1400 Independence Ave, SW
Washington, DC 20250
202-690-6056 - **Phone**
202-720-1815 - **Fax**
E-mail: labbott@oce.usda.gov

Dana Atwell
Manager -Industry & Governmental Affairs
Shell Canada Products Limited
400 4th Ave, SW
PO Box 100 Station M
Calgary, Alberta T2P 2H5 CANADA
403-691-3239 - **Phone**
401-691-2224 - **Fax**
E-mail: dana.atwell@shell.ca

Christine M. Augustyniak
Office of Environmental Information
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-1512 - **Phone**
202-401-2727 - **Fax**
E-mail: augustyniak.christine@epa.gov

Daniel Axelrad
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-9363 - **Phone**
202-260-0512 - **Fax**
E-mail: axelrad.daniel@epa.gov

Donald Barnes
Director, Science Advisory Board
US Environmental Protection Agency
Mail Drop 1400AR
1200 Pennsylvania Ave NW
Washington, DC 20460
202-564-4533 - **Phone**
202-501-0323 - **Fax**
E-mail: barnes.don@epa.gov

Richard Belzer
Center of the Study of American Business
Washington University
Suite 310
819 7th Street, NW
Washington, DC 20001
202-898-2050 - **Phone**
202-478-1626 - **Fax**
E-mail: csabindc@iname.com

Edward Bender
Office of Science
US Environmental Protection Agency
1300 Pennsylvania Ave, NW
Washington, DC 20460
202-564-6483 - **Phone**
202-565-2925 - **Fax**
E-mail: bender.ed@epa.gov

John Bennett
Office of Water
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-0446 - **Phone**
202-260-3762 - **Fax**
E-mail: bennett.johnb@epa.gov

Greg Biddinger
Safety, Health & Environment
Exxon Mobil Corporation
3225 Gallows Rd
Fairfax, VA 22037
703-846-7078 - **Phone**
703-846-2898 - **Fax**
E-mail: greg.r.Biddinger@exxon.com

Lynne Blake-Hedges
Office of Pollution Prevention and Toxics
US Environmental Protection Agency (7406)
1200 Pennsylvania Ave. NW
Washington, DC 20460
(202) 260-7241 - **Phone**
(202) 260-1661 - **Fax**
E-mail: blake-hedges.lynne@epa.gov

Elizabeth Boa
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209
703-741-5234 - **Phone**
703-741-6040 - **Fax**
E-mail: elizabeth_boa@americanchemistry.com

Peter Calow
University of Sheffield
Dept of Animal and Plant Sciences
Western Bank
Sheffield S10 2TN UK
44-114-222-4692 - **Phone**
44-114-278-0694 - **Fax**
E-mail: p.calow@sheffield.ac.uk

Gail Charnley
HealthRisk Strategies
826 A Street, SE
Washington, DC 20003
202-543-2408 - **Phone**
202-543-3019 - **Fax**
E-mail: healthrisk@aol.com

Gary Cole
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-7132 - **Phone**
202-260-1661 - **Fax**
E-mail: cole.gary@epa.gov

Cristina Cortinas de Nava
SEMARNAP
Instituto Nacional de Ecología
Av. Revolucion 1425
Mexico DF
04010 MEXICO
52-5-624-33-91 - **Fax**
52-5-624-35-95 - **Phone**
E-mail: mcortina@ine.gob.mx

Jim Darr
Exposure Assessment Branch (7406)
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-3441 - **Phone**
202-260-0981 - **Fax**
E-mail: darr.james@epa.gov

Paul De Civita
Office of Environmental Health Economics
Health Canada
Ottawa, Ontario K1A 0L2 CANADA
613-952-4582 - **Phone**
613-941-3883 - **Fax**
E-mail: paul_decivita@hc-sc.gc.ca

Chris Dockins
National Center for Environmental Economics
US Environmental Protection Agency
Ariel Rios Bldg, Mail Code 2177
1200 Pennsylvania Ave, SW
Washington, DC 20460
202-260-5728 - **Phone**
202-260-5732 - **Fax**
E-mail: dockins.chris@epa.gov

Jack Donnan
Economic Analysis and Program Support Section
Ontario Ministry of Energy, Science & Technology and Environment
3rd Floor
880 Bay Street
Toronto, Ontario M7A 2C1 CANADA
416-325-6624 - **Phone**
416-325-7023 - **Fax**
E-mail: donnanja@est.gov.on.ca

Elin Eysenbach
The Procter & Gamble Company
PO Box 538707
Cincinnati, OH 45253-8707
513-627-1382 - **Phone**
513-627-1402 - **Fax**
E-mail: eysenbach.ej@pg.com

Sue Ferenc
ILSI Risk Science Institute
1126 16th Street, NW
Washington, DC 20036
202-659-3306 - **Phone**
202-659-3617 - **Fax**
E-mail: sferenc@ilsi.org

Geoff Granville
Shell Canada Limited
400 4th Ave, SW
Calgary, Alberta T2P 2H5 CANADA
403-691-2220 - **Phone**
403-691-2224 - **Fax**
E-mail: granvil@shell.ca

George Haas
Institute of the Environment
University of Ottawa
555 King Edward Avenue
Ottawa, Ontario, KIN 6N5 CANADA
613-562-5800 x 1191 - **Phone**
613-562-5873 - **Fax**
E-mail: ghaas@uottawa.ca

James Hammitt
Associate Professor of Economics and Decision Sciences
Harvard Center for Risk Analysis
718 Huntington Ave
Boston, MA 02115
617-432-4030 - **Phone**
617-432-0190 - **Fax**
E-mail: james_hammitt@harvard.edu

Robin Hill
Health Protection Branch
Health Canada
Room 1185
Ottawa, Ontario K1A 0L2 CANADA
613-941-9740 - **Phone**
613-952-3196 - **Fax**
E-mail: robin_hill@hc-sc.gc.ca

Jean-Willy Ileka
Environment Canada
22nd Floor
10 Wellington Street
Hull, Quebec K1A 0H3 CANADA
819-997-2120 - **Phone**
819-997-2769 - **Fax**
E-mail: jean-willy.ileka@ec.gc.ca

Karen Kohrman
The Procter & Gamble Company
PO Box 538707
Cincinnati, OH 45253-8707
513-627-2670 – **Phone**
513-627-1167 - **Fax**
E-mail: kohrman.ka@pg.com

Alan Krupnick
Senior Fellow and Director
Resources for the Future
1616 P Street, NW
Washington, DC 20036
202-328-5107 - **Phone**
202-939-3460 - **Fax**
E-mail: krupnick@rff.org

Robert Lee
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1300 Pennsylvania Ave, NW
Washington, DC 20460
202-260-1703 - **Phone**
202-260-1661 - **Fax**
E-mail: lee.robert@epa.gov

Mark Lewis
Environment Canada
351 St. Joseph Blvd
Hull, Quebec K1A 0H3 CANADA
819-953-7199 - **Phone**
819-953-4936 - **Fax**
E-mail: mark.lewis@ec.gc.ca

Steven C. Lewis
ExxonMobil Biomedical Sciences, Inc.
Room LG-348
PO Box 971
1545 Route 22 East
Annandale, NJ 08801
908-730-1036 - **Phone**
908-730-1197 - **Fax**
E-mail: sclewis@erenj.com

Des Mahon
Environment Canada
351 St. Joseph Blvd
Hull, Quebec K1A 0H3 CANADA
819-997-3181 – **Phone**
819-953-4936 - **Fax**
E-mail: des.mahon@ec.gc.ca

Elizabeth Margosches
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1200 Pennsylvania, Ave, NW
Washington, DC 20460
202-260-1511 - **Phone**
202-260-1279 - **Fax**
E-mail: margosches.elizabeth@epa.gov

Tim McDaniels
University of British Columbia School of Planning
6333 Memorial Rd
Vancouver, BC V6T 1Z2 CANADA
604-822-9288 - **Phone**
604-822-3787 - **Fax**
E-mail: timmcd@interchange.ubc.ca

Al McGartland
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-5500 - **Phone**
202-260-3354 - **Fax**
E-mail: mcgartland.al@epa.gov

Bette Meek
Health Canada
Room 217
Environmental Health Centre
Ottawa, Ontario K1A 0L2 CANADA
613-957-3129 - **Phone**
613-941-4546 - **Fax**
E-mail: bette_meek@hc-sc.gc.ca

Michel Mercier
ICME
136 Rue Combe De L'Fau
Divonne Les-Bains 01220 FRANCE
011-41-22-799-6497 - **Phone**
011-41-22-799-6878 - **Fax**
E-mail: michel.mercier@eurospan.com

Martha Gilchrist Moore
American Chemistry Council
1300 Wilson Blvd
Arlington, VA 22209
703-741-5928 - **Phone**
703-741-6928 - **Fax**
E-mail: martha_moore@americanchemistry.com

Tom Muir
Environment Canada
867 Lakeshore Road
Burlington, ON L7R 4A6 CANADA
905-336-4951 - **Phone**
905-336-8901 - **Fax**
E-mail: tom.muir@ec.gc.ca

Tosihiro Oka
Professor, Economics
Fukui Prefectural University, Japan
4-1-1 Kenjojima
Matsuoka, Fukui 910-1195 JAPAN
81-776-61-6000 x2705 - **Phone**
81-776-61-6014 - **Fax**
E-mail: oka@fpu.ac.jp

Joan Packenham
AAAS fellow
US Environmental Protection Agency
1400 Pennsylvania Avenue, NW
Washington, DC 20460
202-564-3362 - **Phone**
202-565-0061 - **Fax**
E-mail: packenham.joan@epa.gov

John Pasternak
Environment Canada
4th Floor
224 West Esplanade
North Vancouver, BC V7M 3H7 CANADA
604-666-8077 - **Phone**
604-666-6800 - **Fax**
E-mail: john.pasternak@ec.gc.ca

Brenda Heelan Powell
Environmental Law Centre
10709 Jasper Ave
#204
Edmonton, Alberta T5J 3N3 CANADA
780-424-5099 - **Phone**
780-424-5133 - **Fax**
E-mail: bhpowell@elc.ab.ca

Peter N. Nemetz
Strategy and Business Economics
University of British Columbia
Vancouver, BC V6T 1Z2 CANADA
604-822-8443 - **Phone**
604-224-7386 - **Fax**
E-mail: peter.nemetz@commerce.ubc.ca

Eric Ormsby
Therapeutic Products Programme
Health Canada
2nd Floor
1600 Scott St
Ottawa, Ontario K1A 1B0 CANADA
613-941-3694 - **Phone**
613-941-5035 - **Fax**
E-mail: eric_ormsby@hc-sc.gc.ca

Linda R. Papa
Office of Research and Development
National Center for Environmental Assessment
US Environmental Protection Agency
Room 190
26 W. Martin Luther King Dr.
Cincinnati, OH 45268
513-569-7587 - **Phone**
513-569-7916 - **Fax**
E-mail: papa.lynn@epa.gov

Paul Portney
Resources for the Future
1600 P Street, NW
Washington, DC 20036
202-328-5000 - Phone
202-939-3460 - Fax
E-mail: portney@rff.org

Louise Power
National Office of Pollution Prevention
Environment Canada
351 St. Joseph Blvd
Hull, Quebec K1A 0H3 CANADA
819-994-2335 - **Phone**
819-953-7970 - **Fax**
E-mail: louise.power@ec.gc.ca

Donald Rodier
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-1276 - **Phone**
202-260-1216 - **Fax**
E-mail: rodier.donald@epa.gov

Lorraine Seed
Biologist
Health Canada
EHC-236
Tunney's Pasture 0802C2
Ottawa, Ontario K1A 0L2 CANADA
613-957-9575 - **Phone**
613-941-4546 - **Fax**
E-mail: lorraine_seed@hc-sc.gc.ca

Arthur Sheffield
Environment Canada
22nd Floor
10 Wellington Street
Hull, Quebec K1A 0H3 CANADA
819-953-1172 - **Phone**
819-997-2769 - **Fax**
E-mail: arthur.sheffield@ec.gc.ca

Nathalie Simon
Office of Policy and Reinvention
US Environmental Protection Agency
Mail Code 2177
1200 Pennsylvania Ave
Washington, DC 20460
202-260-1967 - **Phone**
202-401-0154 - **Fax**
E-mail: simon.nathalie@epa.gov

Thomas B. Starr
TBS Associates
7500 Rainwater Rd
Raleigh, NC 27615-3700
919-876-0203 - **Phone**
919-876-0201 - **Fax**
E-mail: tbstarr@mindspring.com

Mark Saner
Carleton University
1125 Colonel By Dr.
Ottawa, Ontario K1S 5B6 CANADA
613-520-2600 x 3942 - **Phone**
613-520-3962 - **Fax**
E-mail: saner@magma.ca

Anne Sergeant
National Center for Environmental Assessment
US Environmental Protection Agency (86230)
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-564-3249 - **Phone**
202-565-0076 - **Fax**
E-mail: sergeant.anne@epa.gov

Richard Sigman
Organization for Economic Cooperation and Development
2 rue André-Pascal
Paris 75775 Cedex 16 FRANCE
33-1-4524-1680 - **Phone**
33-1-4524-1675 - **Fax**
E-mail: richard.sigman@oecd.org

Adam Socha
Ontario Ministry of the Environment
7th Floor
40 St. Clair Avenue, West
Toronto, Ontario M4V 1M2 CANADA
416-327-3912 - **Phone**
416-327-2936 - **Fax**
E-mail: sochaad@ene.gov.on.ca

Akihiro Tokai
Dept. of Environmental Engineering
Hokkaido University
West 8, North 13
Sapporo, Hokkaido 060-8626 JAPAN
81-11-706-7284 - **Phone**
81-11-706-7284 - **Fax**
E-mail: tokai@eng.hokudai.ac.jp

Roger J. Tregunno
Dept of the Environment, Transport & the Regions
Floor 3/E4 Ashdown House
123 Victoria Street
London SW1E 6DE UK
44-20-7944-5266 - **Phone**
44-20-7944-5229 - **Fax**
E-mail: roger_tregunno@detr.gsi.gov.uk

Vanessa Vu
Office of Research and Development
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-564-3282 - **Phone**
202-565-0066 - **Fax**
E-mail: vu.vanessa@epa.gov

Mary Ellen Weber
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-260-0667 - **Phone**
202-260-0981 - **Fax**
E-mail: weber.maryellen@epa.gov

David Widawsky
Office of Pesticide Programs (7503C)
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
703-308-8150 - **Phone**
703-308-8091 - **Fax**
E-mail: widawsky.david@epa.gov

M. Alfred Wiedow
Director of Toxicology
CIBA Specialty Chemicals Corp
Room 620
560 White Plains Rd
Tarrytown, NY 10591
914-785-2438 - **Phone**
914-785-4074 - **Fax**
E-mail: al.wiedow@cibasc.com

William Wood
Risk Assessment Forum
US Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
202-564-3358 - **Phone**
202-565-0062 - **Fax**
E-mail: wood.bill@epa.gov

Annex 3. Breakout Group Assignments

Participants

Roles	Group A	Group B	Group C	Group D
Co-leader	Jack Donnan	Sue Ferenc	Christine Augustyniak	Peter Calow
Co-leader	Donald Barnes	Marc Saner	Tim McDaniels	Cristina Cortinas de Nava
Rapporteur	Richard Sigman	Gary Cole	Robin Hill	Martha Moore
Rapporteur	Geoff Granville	Tom Muir	Thomas Starr	Anne Sergeant
	Greg Biddinger	Edward Bender	Linda Abbott	Dana Atwell
	Elizabeth Boa	John Bennett	James Hammitt	Daniel Axelrad
	Jim Darr	Lynne Blake-Hedges	Steve Lewis	Richard Belzer
	George Haas	Paul De Civita	Elizabeth Margosches	Elin Eysenbach
	Brenda Heelan Powell	Chris Dockins	Al McGartland	Mark Lewis
	Jean-Willy Ileka	Karen Kohrman	Bette Meek	Des Mahon
	Robert Lee	John Pasternak	Tosihiro Oka	Michel Mercier
	Peter Nemetz	Louise Power	Lorraine Seed	Linda Papa
	Joan Packenham	Akihiro Tokai	Vanessa Vu	Natalie Simon
	Donald Rodier	Roger Tregunno	William Wood	Adam Socha
	Arthur Sheffield	Mary Ellen Weber		David Widawsky
		Alfred Wiedow		