New Directions Workshops ***Identifying Information Needs for Risk Managers*** Series

Identifying Information Needs for Risk Managers

Summary Report
for the Workshop Series

June 15-16, 1999
Information Needs for Risk Management Decision Making

July 14-15, 1999
Communication and Stakeholder Involvement in the Risk Management Process

Prepared for

Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

September 1, 1999

New Directions Workshops — ***Identifying Information Needs for Risk Managers*** **Series**

Workshop I:
Information Needs for Risk Management Decision Making

Summary Report

Prepared for

Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

September 1, 1999

Executive Summary

The two workshops that comprised the ORD-sponsored series, *Identifying Information Needs for Risk Managers,* held in June and July of 1999, provided opportunities for EPA managers and staff to engage in a cross-agency dialogue on informing the risk management decision-making process. The two workshops addressed four general topic areas.

- Risk management paradigms/models
- Information needs for risk managers
- Risk assessor–risk manager communication
- Stakeholder involvement in decision making

Workshop participants discussed these topics within two related contexts: (1) informing the decision-making process by bringing all relevant information to bear on decisions, and (2) identifying research opportunities to meet currently unaddressed or future information needs.

Risk Management Paradigms/Models

After reviewing and discussing several diagrammatic representations of the risk management process, including models developed by the Presidential Commission on Risk Assessment and Risk Management and ORD's National Risk Management Research Laboratory, workshop participants indicated that a simple model could provide a useful, if not complete, representation of the risk management process. The utility of such a model would be two-fold. First, it would provide managers with a checklist of information sources and input points, and would identify interactions between actors in the decision-making process. Second, a model would help ORD identify what types of information/research/data are needed, where or from whom to obtain this information, and at what points in the process such information would be most useful to decision makers. To be realistic and useful, a model must also capture the iterative nature of the risk management process and identify key communication pathways.

STATUS OF THIS REPORT

The objective of this workshop (or workshop series) was to bring together EPA scientists from the regions, programs, and ORD labs and centers to discuss issues of common interest. The focus of the meeting (or each meeting) was preliminary discussion among scientists and managers from different parts of the Agency, each with their individual and office-specific information and viewpoints.

As a result, it is important to understand that this report summarizes individual and program-specific perspectives. References to pre-existing Agency information and policies should be credited as such, but none of the individual workshop statements or summaries in this report should be credited or cited as Agency information or policies. Rather, this report is developed exclusively for internal EPA use and distribution as a record of the meeting for participants in each meeting, and for EPA's use in planning future meetings and discussion. EPA staff will use information from this report, as appropriate, to design and conduct workshops or other activities for broader discussion both within EPA and with external participation, again as appropriate.

Information Needs

Panel discussions by senior EPA managers, case study presentations by agency staff, and break-out and plenary discussions by workshop participants identified many types of non-risk-assessment information that factor into decision making at EPA. Such information includes technical feasibility and effective alternatives, the real transaction costs of a decision and resource burdens on the agency, legal issues and statutory mandates, and equity/fairness, to name just a few. In many cases, the risk manager is not an EPA official, but rather someone from a state or local government, the business community, or the general public. The importance of non-risk-assessment information is growing, as stakeholders become more involved in agency decisions and EPA increases its use of non-regulatory approaches to risk mitigation. For the program and regional offices, this means viewing risk assessment as but one of many factors used to formulate a decision or communicate a concern. For ORD, the growing importance of non-risk information points to a possible need for more social science research; it also suggests that, increasingly, the users of ORD research may reside outside the agency.

Communication between Risk Assessors and Risk Managers

When risk assessment is part of the decision-making process, the quality of the decision may hinge on how well the risk assessor and risk manager communicate. Workshop participants noted the importance of early collaboration—planning and scoping and conceptual model development were cited as means to effect early risk assessor–risk manager interaction. While front-end communication between assessors and managers is important, *sustained* interaction is essential. By establishing feedback loops and communication milestones throughout the decision-making process, risk assessors and risk managers can clarify expectations, discuss preliminary findings, and work together to solve problems in a manner that addresses both science and policy issues.

A unified paradigm or model of the risk management process in general, and of information needs in particular, would be useful in facilitating and enhancing communication between risk assessors and risk managers. If both parties share a common understanding of the process, they are more likely to agree on the expectations for each person's contribution to the decision; assessors and managers would also better comprehend the information they receive from one another, since the model would illustrate the context within which the information was developed.

Stakeholder Involvement

Stakeholder involvement is becoming a regular way of doing business for EPA's programs and regions, and must be included in any discussion of informing the agency's decision-making process. Stakeholder involvement requires careful preparation, and is both time consuming and resource intensive. However, decisions made with stakeholder input are not only likely to be better decisions, but may be viewed more favorably by interested parties and be less vulnerable to legal or other challenges. So long as EPA follows through with its commitments to stakeholders, their continued involvement can over time build greater public trust in agency decision making.

For any particular decision, the appropriate role of stakeholders—be it exchanging information, developing recommendations, or participating in joint decision making—should be determined early on and sustained past the decision point through the evaluation stage. An implication for the development of a risk management paradigm or model, then, is the need to determine points in the risk management process where stakeholder interaction should take place, given the nature of the particular risk issue and the extent/type of stakeholder involvement being considered.

Conclusions

Workshop participants did not come to consensus on a preference for any particular paradigm or model of the risk management process. However, it is clear that none of the current models adequately addresses the many different information and communication issues discussed at the workshops. Nor did participants identify specific potential research areas related to paradigms, information needs, communication, or stakeholder involvement. Nevertheless, the rich discussion of these issues, reflected in the body of this report, suggests that the area of information needs is fertile ground for developing new risk management research topics.

Path Forward

While there are many important points made within the body of the report that deserve additional attention, follow-up actions and a time line for next steps have not been finalized. The intent over the next several months is to refine the salient elements of the two workshop proceedings, possibly in a white paper, for further discussions with EPA's Program and Regional Offices, and the Science Advisory Board. In addition, stakeholders may be consulted to gain insights on the risk management process from outside of the Agency. Ultimately, an improved process for making risk management decisions will be of importance not only to EPA, but also to those involved in human health and environmental decisions at the state, community, and tribal levels.

This report was prepared for the Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, by S. Cohen & Associates, Inc., 1355 Beverly Road, Suite 250, McLean, VA 22101, and Environmental Management Support, Inc., 8601 Georgia Avenue, Suite 500, Silver Spring, MD 20910, under contract number 68-D5-0132, work assignment III-8. For futher information, please contact Gerardo Pascual at 202-564-2259.

Table of Contents

Appendices

List of Exhibits

Preface

EPA's Office of Research and Development (ORD) is currently pursuing new approaches for using science to address several topics of importance to the Agency. These topics represent new directions for EPA in that they transcend the traditional media- or pollutant-based boundaries and encompass a variety of disciplines and specialities. ORD wishes to link EPA staff interested in these topics with the appropriate science staff in ORD to identify areas for collaboration. To accomplish this goal, ORD's Office of Science Policy (OSP) is hosting a series of New Directions workshops between March 1999 and Spring 2000. The workshops will provide a forum to present information and discuss current and future issues on new topics of interest. There are four topic series being presented under the auspices of New Directions: risk management, community assessment, reinvention, and regional science. Each topic series will consist of three or four workshops designed to bring interested staff together to develop a set of action items that will be completed over the course of the series.

The Risk Management workshops are designed to identify the types of information, such as costs and benefits, technological feasibility, community values, and other non-risk assessment information, that EPA managers need and use to inform their risk-management decisions. This summary describes the first workshop, held June 15-16, 1999 in Washington, DC; a second workshop was held July 14-15 to discuss communication and stakeholder involvement in risk management. A third meeting may be held, if deemed necessary. The desired outcome of the series is a review and analysis of risk-management processes and information needs for use in the development of a draft unified paradigm for organizing and providing information to risk managers.

The first workshop, *Developing Information Needs for Risk Management Decision-Making*, took the following approach to: (1) Obtain the perspectives of senior managers in the media program offices, cross-media offices, and regional offices on the kinds of information they need to make risk-management decisions; (2) Present work currently being done in ORD and elsewhere on the information-needs aspects of the risk-management paradigm; (3) Examine case studies that offer detailed descriptions of information used to make risk-management decisions; and (4) Use break-out groups to review, evaluate, and recommend improvements to the current draft paradigms/models for providing information to risk managers.

This report summarizes the information that was presented and exchanged during the workshop. The organization of the report follows the agenda of the workshop. Approximately 65 senior EPA staff, representing EPA program offices, ORD, and several Regions, participated; Appendix A provides a complete list of participants. The two-day workshop was designed to maximize participant input and collaboration; Appendix B is a copy of the final agenda. Appendix C provides the instructions to presenters, while Appendix D includes copies of the models discussed. Finally, Appendix E gives transcriptions of flip charts and posters produced during the breakout group discussions.

1. Introduction

The New Directions initiative and the Risk Management series were introduced in a presentation by Timothy Oppelt of EPA's Office of Research and Development (ORD). New Directions workshops are intended to bring EPA scientists, analysts and managers together to discuss how new approaches to environmental protection are being addressed across the Agency. Workshop sponsors believe that these discussions will produce cross-agency linkages that will strengthen science at EPA by fostering collaboration and coordination of scientific issues that cross traditional program and media boundaries.

EPA's Office of Science Policy (OSP) has identified community assessment, regional science, reinvention, and risk management as workshop series subject areas. While these four areas may not cover all the new science directions that EPA is taking, they encompass a wide range of cross-program and cross-media science issues that may serve as potential workshop topics. Each series will be comprised of three to four topic-specific workshops.

With this particular workshop, ORD is seeking to understand how to improve the information managers use to support risk-management efforts throughout the Agency. Current risk management decision-making processes include analyzing information about technical feasibility, performing cost-benefit analyses, and performing a variety of tasks to assess community values. ORD seeks to define what further information a risk manager uses to inform his or her risk-management decisions and to answer questions about how participants, such as States and various stakeholders, fit into the risk-management process.

Environmental protection is moving in new directions. As science has significantly advanced our understanding of single-source environmental hazards to humans and the environment, attention is now turning to the complexities and uncertainties associated with the impact on health and ecosystems that may result from exposure to multiple pollutants through multiple pathways. Thus, an additional goal of this workshop was to evaluate the usefulness and completeness of present risk-management models and to consider new models to work with evolving questions, such as assessing the impacts of pollutants across different media.

2. Panel Discussions

Presenters for the panel discussion segment of the workshop were guided by workshop organizers to discuss the kinds of information needed to make risk-management decisions in their particular program office, how that information is used, and what kinds of information would improve their work. The workshop document *Guidance to Presenters* can be found in Appendix C. Presenters were directed to address the following questions:

- What kinds of non-risk assessment information (e.g., economic; science, other than hazard and exposure data; technological feasibility; environmental justice) does your program consider when making a risk-management decision?
- How is such information factored into the decision-making process?
- How does your program obtain this information?
- Do statutory mandates encourage or limit the consideration of such information. If so, how?
- We are all familiar with the uncertainties inherent in risk assessment. What comparable uncertainties on the risk-management side could be reduced if more information were available to decision-makers?
- Under ideal circumstances, what information, beyond what is currently available to you, would you consider valuable to inform your program's decisions?

The first panel discussed the information needs of the media program offices, while the second examined the information needs of the cross-media and Regional offices. Panel presentations and group discussions are summarized below.

2.1 Media Program Office Information Needs

2.1.1 OAQPS/OAR Risk-Management Information Needs (Sally Shaver - OAQPS/OAR)

Sally Shaver opened the panel discussions by summarizing the activities of the Office of Air Quality Planning and Standards (OAQPS). According to its authorization, Clean Air Act (CAA) Sections 109 and 112, EPA's air program was intended to be strictly based on risk. The Act mandated that the Agency consider health and welfare alone in risk management decision-making; costs were not to be considered. Before 1990, therefore, regulation of air toxics was based on risk and the lack of widely accepted tools and data hindered early efforts. As a result, a limited number of standards were promulgated. However, with the promulgation of the 1989 Benzene rule, OAQPS started to make progress. The Benzene rule set a strong precedent in demonstrating how to set risk-based standards.

The basis of considerations for risk management changed with the 1990 CAA Amendments. Under these Amendments, 188 stationary-source Hazardous Air Pollutants (HAPs) were listed for regulation under technology-based Maximum Achievable Control Technology (MACT) standards by 2002. During the Residual Risk Program phase, which will begin eight years after MACT standards have been in place, the CAA Amendments encourage consideration of an

"ample margin of safety" in risk management decision-making. This means that many factors other than health risk, such as cost, impact on industry, and who is impacted by exposures, can now be considered.

Currently, OAQPS has completed half of the work of setting MACT standards for the 188 stationary-source HAPS. In addition to the remaining HAPs, OAQPS is also evaluating the need to regulate mercury from coal-fired utilities. The Office is studying the deposition of mercury to waters covered in the Great Waters Program. Further, Urban Air Standards have been expanded to include mobile sources and OAQPS is mandated to achieve a 75% reduction in the incidence of cancer risk from these sources.

Under the MACT program, cost and other factors may be considered in risk determinations with technology-based standards. Eight years after MACT promulgation, residual risk standards are to be considered. OAQPS is designing an assessment for three more categories to determine if there is a need to regulate. These three categories are:

- Linear carcinogens.
- Nonlinear carcinogens (i.e., one for which there may or may not be a safe exposure level) and non-carcinogens.
- Ecological risk (which is being developed as an interagency effort).

The statutory mandates discussed above both limit and encourage the uses of non-risk assessment information. The CAA Amendments mandate that OAQPS use the "ample margin of safety" framework put in place before 1990. The "ample margin of safety" considers a balance of health risk information with other considerations, such as economics, technical feasibility, and population-related information. Non-risk assessment information considered by OAQPS during the risk-management process includes:

- Technical feasibility - Can technology reasonably be expected to be a control mechanism?
- Cost - Are control costs reasonable in comparison with health benefits expected?
- Industry impacts and potential job losses - Will the regulated industry be damaged economically by the regulations?
- Subpopulation impacts - Which populations are being exposed to HAPs and at what levels?
- What is the total number of people exposed to specific risk levels?

OAQPS obtains the information it uses for risk-management decisions from internal EPA databases; State, regional, and Federal agency sources; industry (both voluntarily and during compliance negotiations); and other stakeholders. OAQPS also conducts its own analyses. Residual risk is considered in the "ample margin of safety" step of risk assessment. This allows OAQPS to develop health standards that are more stringent to increase public health protection balanced against other considerations and use ecological cost and effects information to justify decisions.

Uncertainties in performing risk management with regard to costs could be reduced by having more information about costs and impacts, as well as by having current economic information validated by further research and testing. In addition, more information is needed to determine the true impact of regulations on industry. Uncertainties in health risk assessment could be reduced further by obtaining better human health risk information and addressing the quality control of the data. Although some data exist for carcinogens, non-carcinogens have not been addressed rigorously. Uncertainty could also be reduced by better understanding the contribution of sources to cumulative risks. EPA still does not have the tools to look at cumulative risk from combined sources in air (known as "air soup") and the effects of multi-media exposures.

OAQPS does not regulate indoor air; however, by regulating pollutants in outdoor air, indoor air quality is improved, since indoor air is ventilated using outdoor air. Clean outdoor air and properly ventilated buildings therefore help maintain good indoor air quality.

2.1.2 Pesticide Management Risk Assessment (Marcia Mulkey - OPP/OPPTS)

EPA's Office of Pesticide Programs (OPP) makes a high number of risk decisions in the assessments it conducts each year as it evaluates new chemicals, new uses proposed for known chemicals, and emergency registration uses. OPP also analyzes chemicals made before 1984. Unlike some programs, OPP does not lack data. Information for risk management decision-making comes from an in-house, robust and comprehensive chemical database, with some database information supplied by formulators. OPP also has good chemical usage data.

OPP operates under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Office also operates under the Food Quality Protection Act, which is not a risk benefit statute. This statute directs that there be a "reasonable standard of no harm" used in considerations and is used to decide when to regulate. In risk assessment decision-making, the Food Quality Protection Act mandates that OPP aggregate all public exposure sources and perform cumulative risk assessment for pesticides.

The kinds of enhanced or new data that would help OPP better perform pesticide risk-management assessments include non-risk related data, such as stakeholder polling. Ideally, this effort would define who the stakeholders are for a given effort, what their opinions are, and how and at what levels the Agency should engage stakeholders in the risk-assessment process.

Additionally, OPP could benefit from more information about the real transaction costs of performing Agency business in pesticide risk management. For example, OPP needs ways to ascertain how much political involvement will be required in a given risk-assessment transaction. Even in a cost/benefit analysis, the risk assessor needs to understand the context of the issue, including the influence of interest groups. To be successful, the Office needs to have a realistic expectation of the resource commitment that will be required by political involvement. OPP needs better political information and expertise, but the method of developing this kind of information is not clear. One starting point might be research into the intensity of feelings about pesticide issues.

OPP also needs to have information about other resource burdens associated with a given risk-management decision. It would be useful to have information about total economic costs,

including a true quantification of externalities. For example, promulgating a complex rule means that resources will be committed to explaining it for the following five years. A true cost accounting would allow risk managers to evaluate whether these resource requirements are best used to achieve a relatively small reduction in risk. Small gains may warrant the resource commitment, but OPP must know the burdens to make conscious risk-management decisions.

Information about the results of risk-management decisions can be gathered through enforcement data. However, those who write the standards and those with the ability to implement and enforce them are not the same. This results in a lack of ownership of standards enforcement once standards are promulgated. There should be a tight feedback loop to ensure that EPA promotes coordination between regulators and enforcers.

The issue of marketplace fairness also factors into the risk management decision-making process. Agency efforts can rapidly distort the marketplace, depending on the impact of regulations. OPP tries to maintain a level playing field among industries. Eco-justice is essentially an issue of redressing past unfairness, endeavoring to be fair in the present, and striving not to create future distortions. Further considerations factored into decision-making are geographical and international fairness. It would be helpful to develop sources of information about our stakeholders aside from that provided by Washington lobbyists, who can give a distorted view. OPP has benefitted from communicating in other ways. For example, OPP has successfully approached the fifteen research and development pesticide companies that make up a large part of the regulated community, to explain Agency actions and to gather information. Risk management requires a great deal of information to enable conscious decision-making and the factors discussed above are as important as the hard science issues to the success of OPP.

Science information needs include better understanding of safety factors, such as the limitations of extrapolating risk from laboratory animals to humans and the implications of single-gender data. Data quality within OPP would benefit from more data about ecological effects, such as population level impacts in ecosystems, and not simply human effects. To calculate risk precisely, risk assessors need to know sensitivity endpoints in the ecosystem.

Group discussion focused on the effect of the mandate to reassess pesticides in food under a tight time line. To address this mandate, OPP chose to address the worst situations first. Now, OPP is considering the remaining substances, as well as cumulative effects, under a tight deadline. This has a higher degree of difficulty than the Office's earlier efforts.

The cumulative risk process in OPP involves an evaluation of a cluster of pesticides that operate across media. This is different from considering mixed sources, such as "air soup," which is a mixture of sources operating within the same media. The SPC Cumulative Risk Subcommittee is now assisting the Agency in addressing these types of issues.

2.1.3 Risk Management in OSW (Elizabeth Cotsworth - OSW/OSWER)

The risk-management issues faced by the Office of Solid Waste's (OSW) program are similar to those encountered by the other programs presented above. The waste program uses risk assessment to designate what portion of the waste stream should be dealt with as hazardous waste. Kinds of risk-assessment information considered during these determinations include:

- Legal
- Ecological
- Treatment factors or the effects of technology in the disposal process
- Cost

OSW first determines if there are other statutes and regulations that will address the waste in question. If not, specific OSW risk-management considerations include the potential for future changes in conditions, such as the failure of a landfill liner, cover, or managed systems. The OSW risk-management process takes into account hydrological changes, with the overall goal of using information to think through risk-management decisions consciously.

The implementation factors important to OSW are compliance and enforceability. Flexibility in permitting does present difficulty for enforcers; in fact, in one case, a contingent management approach was dropped due to this difficulty. However, OSW is still carefully using contingent management approaches in some cases. OSW also takes into account State and Resource Conservation and Recovery Act (RCRA) program implementation and enforcement input. OSW endeavors to create simple scenarios for the States that can be implemented with the resources actually available.

Potential vulnerability to legal challenges is a factor in OSW risk assessment. For example, RCRA standards must be based on scientific studies to estimate toxicity. In risk management decision-making, OSW endeavors to track changes to previous decisions so that these changes can be defended and that any precedents that are set are done so consciously. Statutory mandates are a limitation for OSW risk management because of the demands of deadlines. Time limitations sometimes affect the gathering of information needed to inform risk management decision-making.

In the areas of economics and technology, OSW is not mandated to look at cost in risk assessment. However, cost is considered in cost-benefit analyses. In the Hazardous Waste Combustion rule, cost-benefit factors are explicitly detailed. In cost-benefit analyses, OSW considers small business impacts and evaluates the potential for plant closings. The effects of treatment or technological factors are also considered in risk management decision-making. The RCRA "land ban" section mandates that EPA think about using technology by constituent and type of waste.

Group discussion centered on defining how OSW evaluates the impact of decisions and transfers knowledge about its program in-house. While OSW has not created a diagram or flowchart of the risk-management process it follows, risk managers work from anecdotal oral histories and mentors teach new people. OSW has recently begun an effort to improve program planning, scheduling, and documentation of risk-management decisions for future reference.

2.1.4 Information Needs for Risk Management Decision-Making (A Wetlands Manager's Needs) (John Meagher - OWOW/OW)

Authorized by the Clean Water Act (CWA), the wetlands program is working with many of the same risk factors that have been discussed above, including transaction costs. EPA's Office of Wetlands, Oceans, and Watersheds (OWOW) is developing the science of wetland protection and can help partners in the States and in industry who actually implement wetlands protection

work. OWOW activities rest on the basic premise of watershed management, which changes the program from previous end-of-pipe approaches to the present focus on non-point sources. OWOW believes that the program must involve all stakeholders in integrating environmental resources and diverse land uses in a manner that balances ecological, social, and economic needs.

OWOW uses many kinds of non-risk information to evaluate potential pollutant impacts. This includes defining what roles individual and collective wetlands play in the life of a watershed and performing "environmental sociology." This refers to gathering information regarding the overall ecological, social and economic goals of stakeholders. Other non-risk considerations factored into decision-making include environmental justice, economic feasibility, archaeology, historic and tribal sites, and local zoning ordinances.

Additionally, OWOW identifies and evaluates alternative sites and strategies for corrective actions that can reduce environmental impacts. OWOW risk managers consider whether it is economically feasible to move projects and evaluate engineering methods to minimize impacts. Because wetlands damage can potentially be offset by creating a new environmental function elsewhere, OWOW collects information to evaluate potential wetlands replacements.

OWOW considers economic feasibility by looking at methods that will increase the success of restoration, such as aggregating restoration in a watershed using mitigation banking. To use these kinds of compensatory tools, OWOW develops information about where to locate a created wetland within a watershed; what types of restorations are priorities; and what performance criteria are appropriate for the restoration site. OWOW also makes determinations, such as feasibility analyses, to determine whether alternatives are economically and logistically possible.

Stakeholders bring information to the risk-management decision-making process at all phases; participation is encouraged at every stage, from plan selection to iterative actions during which data-gathering occurs, to monitoring, and finally to management for the long term.

Statutory mandates encourage the consideration of these kinds of non-risk information by giving OWOW management tools and authority. The Clean Water Act (CWA), local ordinances and financial incentives help to reduce or offset impacts. Section 404 of the CWA, for example, states that no discharge of dredged or fill material can be permitted if a practicable alternative exists that is less damaging to the aquatic environment, or if the Nation's waters would be significantly degraded. Section 404 also calls for alternatives analyses to either avoid or minimize impacts, or require compensation for unavoidable impacts. Such mandates can be limiting, however. The Constitutional "takings" issue requires that the Government provide compensation to private landowners before depriving them of the use of their land, which has caused controversy with wetlands regulation. This presents a financial limitation on the protection of privately held wetlands.

OWOW obtains risk-management data from EPA-internal databases, the United States Dairy Association, the United States Geographical Survey, State and local governments, and from applicants to the regulatory program. Further kinds of information that would aid OWOW/OW in making risk assessments include data about methods for predicting landscape development trends, such as appropriate distances for setbacks; methods for implementing best management practices; methods for determining width and kinds of buffer strips; and methods for restoring

wetlands. OWOW is now using Geographic Information System data to make future projections in these areas.

Information needs for performing Section 404 work include methods for evaluating and minimizing the consequences of losing a given wetland, methods for developing alternatives to proposed impacts, and methods for reducing the effects of wetland development on wildlife and water quality, including migratory corridors and habitats. OWOW also needs data about healthy wetlands to define the healthy ambient levels for reference wetlands in different climates. The Office of Research and Development could provide research on the science of wetlands creation and methods for reducing risk from flooding.

Group discussion focused on issues of stakeholder involvement and influence. Given the desire of people to live throughout watersheds, how can OWOW regulate against such strong stakeholder pressure? While pressures are strong, there is an increasing recognition of the value of wetlands. Wetlands themselves can be a marketing tool, as they represent open space for those who would like to live in such an area. OWOW is working on forming relationships with the insurance industry, which has an economic interest in mitigating potential flood damage, to defend regulations. The head of the Federal Emergency Management Agency (FEMA) is also taking a strong interest in the wetlands issue, since it makes sense from planning, ecological, and cost perspectives for the Federal flood insurance program.

2.1.5 Risk Management in the Effluent Guidelines Program (Bill Anderson - OST/OW)

The Effluent Guidelines Program, established under the Clean Water Act, resembles the MACT program described in Section 2.1.1. Mandates guiding this program require that risk evaluations consider technology-based standards along with economically-achievable results. Industries or point sources regulated under this program are required to meet numeric limits. Technological controls and remedies are not specifically designated, and the regulated community can meet the numbers required in their permits in the way that they choose.

The Office of Water's (OW) Office of Science and Technology (OST) collects a broad array of data to inform risk-based decision-making, including engineering, economic and environmental information. Engineering data include the ages of facilities; proposed process changes; best pollutant removal or process changes; evolving control technologies; energy usage; and other information from stakeholders. Pollution-prevention principles are also considered and were, for example, built into the *Pulp and Paper Rules* co-authored by OST. Some data is acquired through permit disclosures, but not all of it. While OST can collect any data needed, decisions are made under a tightly scheduled consent decree. Because of this, outreach to stakeholders to provide voluntary data is becoming more critical.

The economic factors considered for risk management include data about facility closures and the potential for facility shutdown, as well as the Agency's exposure to litigation. According to economic guidelines specified by Executive Order, rulemaking must incorporate a full environmental assessment that includes cost-benefit analysis. However, the fact that economic information is not to be used as an explicit criterion for decision-making poses a challenge to the risk-management process.

The environmental data collected includes information about fish kills and water use warnings, water quality standards for a given area, human health impacts such as cancer incidence, and reductions in biological systematic effects. To limit uncertainty as much as possible, more data are needed on assessing impacts on the functioning of biological systems.

As discussed above, statutory mandates encourage consideration of many factors in the risk management decision-making process. The Paperwork Reduction Act, however, restricts the Division from getting data from regulated facilities with reasonable speed.

Group discussion explored the economic feasibility of attaining zero-percent discharge, concluding that it would be very difficult to achieve with reasonable cost. Older limits are not based in reality on zero-percent discharge, because at this time it is not technologically possible to achieve this limit. Therefore, using the Best Available Control Standards (BACT) is most likely to produce the best results. BACT engineering approaches have been integrated into facilities and are near to achieving all possible pollution control at the end of the pipe. Internal process changes, rather than end-of-pipe controls, are yielding more gains.

2.1.6 Information Needs for Risk Management Decision-Making – The Superfund Perspective (David Cooper - OERR)

The pace of clean-ups performed at Superfund sites is increasing, reflecting gains from past experience with Superfund site remediation. Remedial construction has been completed at 43 percent of Superfund National Priority List sites nationwide. Construction is underway at an additional 33 percent of sites. Consequently, the EPA Office of Emergency and Remedial Response (OERR) is beginning to focus on the end of the program, when only a relatively small number of sites (40) will be listed annually. The sites that remain will likely be problematic, as remediations that are more easily achieved have been completed.

Themes guiding the work of the Superfund program are: (1) to protect health and the environment; (2) that every site is unique and requires a local focus; and (3) that responsible parties pay. Information gathering driven by these considerations includes data about remediation technologies and how best to enact technology transfer; information about functioning in local, multi-jurisdictional, multi-stakeholder settings; communicating guidance to all parties; and data about responsible parties needed to obtain funds for Superfund work.

The first statute authorizing Superfund activity has now expired and the program is now operating under the National Contingency Plan of 1991. This plan does not require the cost-benefit analysis mandated under the original statute. Economic information is considered in risk management decision-making but does not necessarily drive decisions. The bulk of Superfund activity is directed toward remedial investigations and feasibility studies. Treatment and containment alternatives are considered, although treatment is preferred. These alternatives sometimes run counter to cost-effectiveness considerations. Remedies are selected based on the long-term effectiveness of clean-up, health protection, ability to minimize untreatable wastes, use of innovative technologies if they are best, and the most costly aspect of remediation, the ability to return groundwater to beneficial uses. Additionally, all standards promulgated by other Agency offices, as well as State regulations, apply to Superfund activities.

All this information is factored into the risk management decision-making framework, which is evaluated against the following criteria:

- Threshold Criteria:
  - Overall protection of human health and the environment
  - Compliance with applicable or relevant and appropriate requirements

- Primary Balancing Criteria:
  - Long-term effectiveness
  - Reduction of toxicity, mobility and volume
  - Short-term effectiveness
  - Implementability
  - Cost

- Modifying Criteria:
  - State acceptance
  - Community acceptance

Thus, risk management for Superfund is arriving at decisions that balance effectiveness with Implementability, cost, and State and community acceptance.

Ideally, the following kinds of scientific data would help risk-management decision-making and reduce uncertainties associated with this program. Studies of human health effects of special populations, such as children, would be useful. The program would also benefit from a process of validation to give decision-makers confidence in the data by answering questions about site concentrations compared to ambient levels and the effectiveness of selected remedies. This, in turn, would give feedback about the accuracy of risk-management decisions. Research relating to the issue of cumulative risk is also necessary to fill data gaps. Other data needed include models of contaminant fate and transport patterns within and across media, as well as the effects of natural attenuation.

Economic data needs include information about the cost-effectiveness of various cleanup technologies and strategies and quantification of the economic benefit of site clean-up. Future concerns include the need for data about the long-term cost of pollutant containment, forecasting of future land use and the ability to enforce institutional controls long-term. Surveys of stakeholder opinions are also useful. Gathering this information will become even more of an issue as the States take over management of Superfund sites.

Group discussion focused on clarifying the issue considering cost-effectiveness in risk decision-making. The definition of cost-effectiveness under this program is somewhat nebulous, since risk reduction is balanced with long-term clean-up and containment effectiveness. The risk assessment and feasibility study process has been based on generic cost estimates of technological remedy selection in the past. Now that there is an experience base from which to draw, the program is moving toward using performance evaluations during the remedial design phase.

2.2 Cross-Media and Regional Office Information Needs

2.2.1 Needs for Risk Managers in the Reinvention Context (Jerry Phiben - OR)

Jerry Phiben of the Office of Reinvention (OR) opened the panel discussion by speaking to the need for creating accessible and relevant information for those making risk-management decisions outside of EPA. As EPA reinvents itself, EPA will need partners outside the Agency to succeed with new challenges. These partners will come from communities and from industry. The ability to address new problems means that the Agency will have to inform and guide decisions in various places, and form what could be called "Partnerships for Progress." Decisions will be made at the local, facility, and individual level.

The Agency will be dealing increasingly with non-point source problems. It will be important to encourage community members to see themselves as partners in controlling non-point source pollution by providing information that is accessible, understandable, usable and targeted to the needs of the community. All information that Agency programs suggest for the use of community members should pass the test of being understood by non-experts. Community partners are able to understand uncertainty if it is properly explained.

In addition, Agency information should not be limited in scope by media, as community concerns often cut across different media. Community concerns are united in that they are about one place, not one medium. Health, quality of life, cost, and children's health will all be areas in which accessible information for sound decision-making will be needed. One example of consideration based on place exists in the "Eastward Ho" movement, which is a term used to sum up the idea of focusing on redevelopment of older eastern cities instead of promoting new development in the increasingly developed western United States.

To be effective in providing information to communities and influencing risk management decision-making at this level, the Agency will have to develop more social science tools to influence community opinion One example of this kind of tool already exists in the *Community Profiling Guide*. Toward this end, the Science Advisory Board is adding non-economic, social scientists to its members

During group discussion, participants asked about external feedback concerning the Agency's reinvention initiative and the ability of EPA to lead communities by providing information. There are indications that Congress thinks that it is a good idea for EPA to address the States in the ways detailed above. EPA intends to lead through community influence, which requires the Agency to understand community needs. By so doing, the Agency will assist the community in defining its needs.

2.2.2 Risk Management in OPPT (Mary Ellen Weber - OPPT/OPPTS)

Risk management in the Office of Pollution Prevention and Toxics (OPPT) rests, in part, on the premise that, given a choice, people will use safer chemicals. Risk managers, regulators, scientists and engineers can be powerful risk managers because they make the decisions to reduce or avoid use of harmful substances. The kinds of information needed to make good risk-management decisions include data about "green chemistry" and how to apply "Design for the Environment" principles to formulations and processes. EPA can play a vital role by making the risk involved in business decisions explicit in the areas of:

- Compliance
- The use of unregulated chemicals
- Multi-media impacts of chemical choices
- Worker health risks associated with chemical use choices
- Total cost accounting
- Cost, risk, and process and environmental performance of chemicals

Because of its oversight of an entire industry, EPA can bring groups together to capture the economies of scale that make it economically feasible to test new technologies that can then be promoted for use by smaller businesses. One example of this kind of effort exists in the "green chemistry" engineering research done to find solutions to the problems presented by the use of Perchloroethylene (PERC) in dry-cleaning. Liquid carbon dioxide has been identified as a less harmful substitute that is a good catalyst and cleans clothes.

Uncertainty in risk management decision-making could be reduced through research into the changes associated with hazardous effects at the molecular level. What, for example, makes a substance toxic – does it metabolize in a way that is toxic? How does toxicity relate to a substance being water soluble or persistent? Obtaining more information about safer chemistry would allow OPPT to design more effective risk-management tools and rules. OPPT also demonstrates that using Design for the Environment concepts is valuable to industry because it can improve compliance rates, reduce worker risk, reduce costs, provide a competitive advantage, and help companies avoid liability.

The mandates of the Toxic Substances Control Act (TSCA) allow the Agency to consider a variety of risk-management options and factors. Business managers are the real risk managers. EPA can inform and coerce, but, ultimately, the work is done outside the Agency. Successfully partnering with industry stakeholders is effective if OPPT maintains a focus on small clients and does not promise regulatory relief as part of the incentive to partner. As a partner, OPPT obtains cost information, product and performance evaluation information, and defines liability issues associated with the use of alternatives. The "Flexography Project" is one successful example of partnering with industry. This project identified environmentally cleaner inks with equal performance capability for use by printers. The printers involved in the project were small businesses and could not have afforded experimentation individually. The project also produced a readable, two-page case-study pamphlet based on Design for the Environment principles.

Group discussion dealt with questions about information delivery and defining the scope of "green chemistry" activity. One method OPPT uses to deliver information is to "train the trainers," such as trade associations, ecological groups, and equipment suppliers, through seminars. Participants suggested that EPA could stimulate the creation of a new small entity to get this information to a wider audience than EPA can currently manage. In addition, to build trust and communicate across sectors, OPPT endeavors to learn about critical industry issues. These issues can relate to avoiding regulation, working with suppliers to giant industries, or other topics of industry interest.

Life-cycle assessment is incorporated into "green chemistry" as OPPT tries to generalize about the effects from certain structures, not just specific compounds. OPPT does not endorse partners in using "green chemistry" market labels, but partners receive a certificate. In addition,

formulators, such as detergent manufacturers, who remove chemicals of concern from their products can promote this in their marketing.

2.2.3 Information Needs for Risk Management Decision-Making- A Regional Office Perspective, (Stan Laskowski - Region 3)

Current crosscutting issues in Region 3 include mountain top removal mining and valley fills, urban sprawl and related transportation concerns, wetlands protection, and watershed/ coastal concerns. Risk management decision-making plays a role in each of these areas. For example, stakeholders in the area of sprawl include local and county planners, the Department of Transportation, the States, and EPA. The Office of Surface Mining, the Fish and Wildlife Service, the Army Corps of Engineers, the public, industry, and groups like the Natural Resources Defense Council are stakeholders with regard to mountain top removal mining. EPA can affect risk-management decisions through data dissemination to the stakeholders.

The kinds of information needed for risk management decision-making in Region III are data correlating landscape and associated environments; assessments detailing cumulative effects; data about the effect of multiple stresses on aquatic resources; real-time indicators to enhance monitoring and other measurements; economic data; and information about social and environmental justice considerations in the Region.

Useful data about landscape and environmental correlation would involve assessing forest cover, impervious areas, slopes and other features, and aligning that with data about environmental indicators, including water quality and songbird and aquatic life representations. Region III is beginning to build a body of information that shows real correlations. For example, having over 21 percent of a given landscape be made up of impervious surfaces means that the area will have no brook trout. This is the kind of risk-management information Region III wants to distribute to decision-makers.

Good risk-management information for cumulative effect assessments involves methods to define geographic boundaries for use in Environmental Impact Statements, and methods that will enable solid future projections about land use impacts. It is necessary to know how to evaluate impacts over time and define the capacity of a given area to withstand impacts.

For the effective management of watersheds, including coasts and estuaries, risk-management information used for decision-making ideally will include methods that define how much aquatic loss is due to various stresses, such as land use changes or over-fishing. In defining the actual causes of the stresses, risk managers can target which stresses can be controlled, define the costs and benefits associated with that control, and determine the chance of success of a given control effort.

Information needed for good risk management decision-making in the area of cost and environmental justice in Region III is focused on the economics of coal mining and the recreation industry. Region III needs site-specific data as well as macro, or interstate, economic impact data. ORD has been a major supplier of information in this area.

2.2.4 EPA's Framework for Community-Based Environmental Protection (Border 2000 Project) (Hal Zenick - NHEERL/ORD)

The EPA document *Framework for Community-Based Environmental Protection* posits that environmental protection is a process, not a program. Risk-management opportunities are presented at all stages of the process. Gathering community information is critical to the process and to fulfill this requirement EPA might consider putting together a community science team.

The border between the United States and Mexico presents special risk-management challenges. EPA became concerned after community cancer rates and birth defects were found to have occurred in disproportionate numbers. To factor needed information into the risk management decision-making in this area, the National Health and Environmental Effects Research Laboratory (NHEERL) used a priority setting or decision tree approach. The result is a research plan to work with the community to define the problem or problems. The goal is not to reach a consensus, but to approach one. The underlying principle is to work with stakeholders at the beginning of the process to understand the possible scenarios that could explain their concerns. EPA must be clear that existing science will not necessarily be able to demonstrate causation unequivocally, and that it is a misrepresentation to say that it can do so.

The quality assurance performed for the purposes of project planning must be as rigorous as that performed for actual project implementation. This is due to the threat of litigation and adds an accountable expense. Community-based work is more successful if there is a planning group with no more than eight to 10 members involved from the beginning of the process. Larger groups may become unmanageable and impede progress. The effectiveness of public meetings is limited due to their size, and media notices do not always work to inform the public. Ideally, program managers must meet with small groups of people. Stakeholder relations in performing community-based work are an ongoing challenge and Federal travel restrictions increase the difficulty of scheduling face-to-face interactions.

Public health concerns are often overlooked in economic considerations, resulting in underestimated costs. To be effective in community-based work, strong relationships with public health agencies must be developed. The Agency must be able to refer people to the appropriate resource to address their problems. rather than expecting the public to accept that the problem is out of the Agency's scope.

While there is a tradeoff between achieving consensus and moving forward toward meeting program goals, a program cannot give up on the notion of consensus. EPA should set quantitative goals to measure its progress in consensus-building. Program managers must be sensitive to the dual roles played by community representatives. They can appear to take seemingly contradictory public and private postures when they are promoting community desires within the risk-management framework.

3. Presentations

3.1 Evolution of the Risk-Management Paradigm (Hugh McKinnon, ORD; Lee Mulkey, ORD)

The current focus of EPA's Office of Research and Development (ORD), which was reorganized in 1995, is to define how it can meet the research needs articulated in the Agency through workshops such as this on risk management. It is necessary to define what ORD needs to do to develop the risk-management paradigm or models needed for present and future work. During the Agency's 20 years of performing risk assessments, risk-management considerations have been added to the equation. Although historically these efforts have been risk or technology driven, it is necessary to look more deeply at social and economic drivers. An article by Powers and McCarthy, which appeared in the May 1, 1998 issue of *Environmental Science and Technology*, presents a comparative analysis of environmental and risk-assessment frameworks (see Appendix D).

The National Research Council model is based on a repetitive analysis process leading to decision-making and other risk-management activities. The Presidential/Congressional Commission, in a study on risk assessment and risk management, produced a model that defines risk, options, and evaluation steps. These models are useful but may be too simple for the kinds of risk-management activity performed by EPA. EPA's Science Advisory Board is currently working on a model of risk reduction options to be used as a process for making decisions. This model is a follow-up to the SAB's *Unfinished Business* report.

A series of risk assessment and risk-management models are presented in the handouts entitled *Paradigm Puzzle Pieces* and *Risk-Management Models* (see Appendix D). The first of the paradigm "puzzle pieces" is the risk assessment or risk characterization phase. The definition of a risk-management evaluation is an analysis of the sources of a potential or assessed risk, the options for reducing the potential or assessed risk, and the availability, costs, and effectiveness of the identified options.

Process representation is well understood. Process steps imply scientific activities. Guidelines for the risk characterization process are in place and pending assessments are peer-reviewed products usually characterized as input to decision-making. Uncertainties are increasingly characterized as the ability to do so evolves. Reducing uncertainties sets new priorities for science. Risk managers are increasingly trying to get quantitative data where previously only qualitative data were available.

Risk management can be said to be the second piece in the paradigm puzzle. This is the point at which uncertainties arise. It is the point at which the scientific data, engineering, cost, and socially based factors, such as policy and legalities, merge. To resolve potential areas in which information is not clear, the risk manager must consider all technical and scientific dimensions of uncertainties. This will include process elaboration, defining scientific and technical steps, defining what the risk-management product will be, characterizing uncertainties, and targeting research to reduce uncertainty.

Components of an assessed or potential risk-management evaluation include defining the who, what, and where of a potential risk. The timing of a risk must also be defined to answer

questions about how the risk will change over time. An example of this exists in the use of emission estimation techniques. A second component is identifying risk-management options. These have increased in number as the Agency has matured. Considerations in this area involve evaluations of effectiveness and cost. In addition, the Agency is considering ways in which the knowledge derived from certain activities can be made commercially available to offset costs.

There are uncertainties in risk management that affect outcomes. As a next step, ORD is going to conduct four pilots on four very different topics to test its model of risk management. These topics will address areas involving air, water, and soil, such as the occurrence of arsenic in drinking water and the *Pfisteria* problem.

Group discussion focused on identifying the reason for the difference in process flow between risk assessment and risk management. A risk assessment is concerned with identifying baseline risk. However, the management of a risk that is identified involves spending scarce resources; the best use of those resources involves other considerations, including social and economic factors, among others.

3.2 A Few Thoughts on Risk Analysis and Risk Management (M. Granger Morgan - Carnegie Mellon University and EPA Science Advisory Board)

Quantified information in risk analysis and risk management must be used to reduce uncertainties as much as possible. However, risk is a multi-attribute concept; people care about more than just a measure of the number of deaths and injuries. Other things that matter include equity, controllability, intergenerational effects and more. Risk managers must insist that risk assessment include these multiple factors. Risk control strategies can be based on modifying human activities, exposures, effects, and perceptions. These strategies can also be based on mitigation or compensation options.

Different risks require different strategies. For example, different strategies are suitable for managing risks associated with auto accident injury versus the risk of getting shot by a handgun. Though both risks can be managed by using avoidance or exposure modification, different strategies are used. In the auto accident example, strategies could involve changing speed limits or training people in defensive driving. In the case of limiting or modifying exposure to control the risk of being shot by a handgun, strategies could involve banning handguns and staying out of high crime areas.

There are now more tools available to reduce uncertainty. There are two kinds of uncertainty: uncertainty about the value of coefficients and uncertainty about basic component functions and functional relationships. Qualitative descriptions are subjective and not adequate for risk management. Meanings vary from individual to individual, according to context, and depending on the knowledge level of the communicator. For example, in a Science Advisory Board survey for EPA, measurements of listeners' understanding of the meaning of the word "likely" varied by as much as four to five orders of magnitude. The probability associated with the word "likely" and that associated with the word "unlikely" actually overlapped. Quantitative discussions can mask differences in what is known about key components in a risk assessment and a lack of clarity among expert opinions can be damaging. Therefore, risk managers should insist on at least some quantification.

In gathering information from and communicating about uncertainty with non-experts, using the "mental model" will help risk managers to: (1) understand what people already know; (2) determine what people need to know; and (3) develop actual messages. The mental model refers to the fact that the very process of finding out what people think can inform them if information gathering is not done carefully. The mental model advocates use of a validated, five-step, interview-based approach. A summary of the five steps is as follows:

- Review scientific knowledge about the risk and summarize it in an influence diagram
- Conduct open-ended elicitation of people's beliefs about the risk using an interview protocol shaped by the influence diagram
- Administer structured questionnaires to a larger set of people to determine belief prevalence
- Draft a risk communication message that is based on an assessment of what people need to know to make informed decisions and addresses their current beliefs
- Iteratively test and refine successive versions of the risk communication before, during and after people are given the message

Experts can analyze and characterize risks to establish risk-management priorities. They have the knowledge to understand all factors involved and to explain the risk in terms that will communicate the complexity of the issue in a way that is understandable to educated members of the public. Representative groups of educated lay-people can be drafted to perform actual ranking because ranking requires the application of social values. Ranking can be performed using two different approaches, either through a holistic consideration of all aspects, or through judgments based on the importance of individual attributes. This process should produce a prioritization that is robust and a product that is useful in risk management decision-making.

To evaluate how risk-management programs are doing, Carnegie Mellon has developed a survey in which experts are asked to provide their evaluations of regulatory performance in their area of expertise in response to structured questions and against provided attributes. Criteria air pollution will be addressed first and wastewater next. A good regulatory system reflects the following attributes.

- Adaptive - integrates new knowledge and transfers to new situations
- Democratic – all parties participatory and informed
- Efficient – timely, cost effective, can be measured, encourages innovation
- Equitable – stakeholders have standing, and costs and benefits are distributed fairly
- Scientifically sound – science used, research encouraged, and uncertainties grasped and communicated

3.3 Day 1 Synopsis

During the first day of the workshop EPA managers discussed the types of non-risk assessment information they factor into their decisions. It was evident from these discussions that information needs vary with individual program and regional activities, but that in nearly all cases the risk assessment is but one factor of many that figures into the decision-making process.

The evolution of the risk management paradigm is ongoing, and in benefitting from many inputs. These include recent work by the Presidential/Congressional Commission on Risk Assessment and Risk Management and ORD's National Risk Management Research Laboratory. Carnegie Mellon University and EPA's Science Advisory Board have also been conducting work on risk management strategies that could factor into further development of a unified model or paradigm.

4. Paradigm Review and Development

4.1 Evaluating the Paradigms, Part One (Tim Oppelt - ORD)

Breakout groups were tasked with evaluating the models summarized in Section 3.1 in terms of the model's usefulness and comprehensiveness for risk management decision-making. Using evaluation approaches such as model-to-model comparison, sorting by information type, or critiquing individual process steps, the groups were to evaluate the model's utility against the information conveyed in the presentations summarized in Section 2. Breakout groups were asked to determine whether and to what extent any or all of the models allow for the development of and integration into a single risk management decision-making process. The groups were asked to consider the question: Do the models capture the needed data and answer information needs such as cumulative risk considerations?

Copies of the models which the breakout groups were asked to evaluate are provided in Appendix D. Flip charts from the breakout sessions are transcribed in Appendix E. Breakout group reports are summarized below.

4.1.1 Reports from the Break-Out Groups, Part One

Breakout Group 1

This breakout group was not monitored by a recorder. However, their report to the plenary group is summarized.

Models are useful in that they can outline the general aspects of the risk-management process and ensure that all parties are have the same understanding of the process. However, while they must be sufficiently comprehensive to be useful, it is necessary to recognize that too many details hamper the flexibility of the model needed to cover a variety of cases. While process steps are similar across cases, problem definitions, decision makers, resource and data needs, and other points will differ. Multi-media, multi-issue problems will require approaches different from that of a single contaminant on a site. In addition, EPA's motivation for performing a risk assessment and making a risk-management decision will differ. In some cases, a decision is mandated by statute, while in others, EPA is attempting to identify a problem that the Agency may have no legal means of resolving.

Breakout Group 2

The group reviewed the descriptions of the decision-making frameworks provided to help define a model to meet the needs of risk managers. Working from the models presented in Appendix D, the group first addressed the Risk-Management Evaluation "Egg" model and then included all the models in generalized remarks.

The critique of models centered on defining the parameters of the risk assessor and risk manager roles, evaluating the comprehensiveness of the models, and documenting how decisions are ultimately made. Overall, the models seemed clear with regard to human health effects assessments, but the role of ecological assessment was not clear.

With regard to task parameters, the models did not clearly designate which steps were to be carried out by risk assessors and which were to be done by the risk manager. For example, in one model, source characterization (which is essentially data gathering) is listed under risk management. Group 2 stated that data collection is more correctly an aspect of risk assessment and that the risk manager should focus the effort and set the questions.

The group discussed whether this was a management or a science issue and made the point that risk-assessment decisions are not clear or separate from politics. This means that one job of the risk manager is to understand all ramifications of decisions and to document the real basis of the decisions that were made. A list of all the factors that should be documented includes social and economic considerations, technical data and political issues. One benefit of this kind of documentation is that it avoids the possibility of setting potentially dangerous precedents by demonstrating, for example, that a given decision was made because of an exceptional circumstance or that it was based on qualitative not quantitative data. Documentation of decisions should detail:

- Program mandate
- Options considered
- Data considered and used
- Uncertainties
- Interactions with internal and external stakeholders

The communication pathway between the risk assessor, the risk manager, and the team as a whole, was also not well defined. Project communication should ideally be structured as an interactive process with regular points of communication designated. Role definitions and communications pathways should be based on risk-assessment/risk-management process and policy and should involve:

- Risk assessors/managers
- Team members
- Public
- Others with input to process

The correct audience for assessment information is those who make decisions at project sites. Risk assessors feel that they must make decisions, but they can only be one-dimensional if they are based solely on risk numbers. Models need to better define the boundaries and communication pathways of the risk manager and the risk assessor. The endpoint of the iterative process should be a well-defined exit strategy.

Group 2 also felt that opportunities to define monitoring were not well established in the models. A process must be articulated to establish what is to be monitored, the types of monitoring to be used, and how monitoring will be used to determine if the assessment has achieved designated goals. Characterizing sources is a critical issue, because it entails an implied policy. Answers to questions about what the issue really is, who is affected, and what are the risk-management goals will affect the designation of resources. Public opinion, though sometimes problematic with regard to science findings, does need to be taken into account on all models and the public should be involved in the review of preliminary findings. Some of the models put this step further along in the process.

Breakout Group 3

The models presented highlighted the processes and information needed to make risk-management decisions and can be considered paradigms for risk management. The group first identified situations in which the concept of one risk-management model might not work to meet risk-management needs. Different ways of using risk management by the different Agency programs may mean that it is not necessary or possible to have only one model. For example, the needs of local community risk managers must be considered - their risk-management needs may be different than those of EPA. Also, individual risk managers may not require all parts of a model for all projects. There are some differences in the way risk assessments are handled by the different offices within EPA, but ecological and human health risk assessments are performed essentially the same way. It is necessary to determine if a comparable situation for risk management exists.

Individual programs need to make different types of decisions using risk management. There are two choices for decision-making frameworks:

- A taxonomy with a complicated system in which system parts are used for different types of decisions

- A simple model for decision-making with a checklist of additional topics to consider

Considering decision-making in this way could lead either to a system of many models that address specifics and includes some method for selecting the appropriate model, or a system with one simple model that can be modified to account for specifics.

Models need to define the linkages between the sources of information (e.g., stakeholder positions, environmental justice). The generation of risk-management options should have a pattern. While there is "mystery" associated with risk management, there should be a way to describe the process in common terms.

Risk assessment requires scientific and technical decision-making to be conducted in a transparent and easily understood way. ORD uses a conceptual view of risk assessment and risk management to make decisions and reduce uncertainty in risk assessment. There seems to be a systematic approach to risk management, but it needs to be described. There may be parts of decision-making that are not meant to be transparent for risk management, while it may be appropriate for other parts to be transparent.

The group listed other sources of input to risk management in addition to risk assessment such as:

- Attorneys
- Chemists
- Economists
- Ecologists
- Toxicologists
- Stakeholders

- Social factors (minimal)

These inputs should be built into a model for risk management. It was pointed out that including politics as an input to risk management might include too much flexibility in the process and destroy any attempt to make the decision-making process transparent. Politics may be better described as the willingness of the public to accept risks and be included as part of stakeholder involvement.

ORD is one source of information for risk managers. Information regarding risk assessment and social and economic considerations should also be gathered. A decision-making team for national-level assessment implemented through regulations should include chemists, chemical engineers, attorneys, economists, and hazard assessors. The team might include biologists, toxicologists, and ecologists. Representatives from the community would not be appropriate for this type of team.

Can risk assessment and risk management actually be part of a single risk-based decision model? Where do risk reduction experts get involved in the process? Risk characterization informs risk management, but not risk-management evaluation and options because of the timing of projects. Additionally, there is uncertainty in the decision-making process. Risk-management decisions are not always simple "yes" or "no" decisions. Any inclusive model needs to account for uncertainty, especially when addressing communities. Different offices have different factors which must not or cannot be taken into account at different steps under different statutes. These limitations should be communicated to the community to help make the process more transparent and provide a better understanding of statutory constraints.

The group then developed a diagram designed to combine parts of existing models (see Exhibit 1). The most important point illustrated is the interaction between risk assessment and risk management.

The group completed the morning discussion with the following summary comments from each group member. Comments regarding diagrams refer to the models given in Appendix D.

- Diagrams that focus on risk management are the easiest to understand. Sequential diagrams may better reflect what EPA currently does with respect to risk management.

- A three-dimensional diagram might be better able to illustrate the process.

- The circular diagrams are preferable as they show inputs to the decision-making process from different areas. Stakeholder involvement is critical.

- The circle within a circle diagram is a good representation, but there should be a way to show the iterative process between risk assessment and risk management.

- Stakeholder input, stakeholder education, economics, and social concerns should have increased emphasis in the decision-making model.

- Simple models are the best. Complicated models intimidate people.

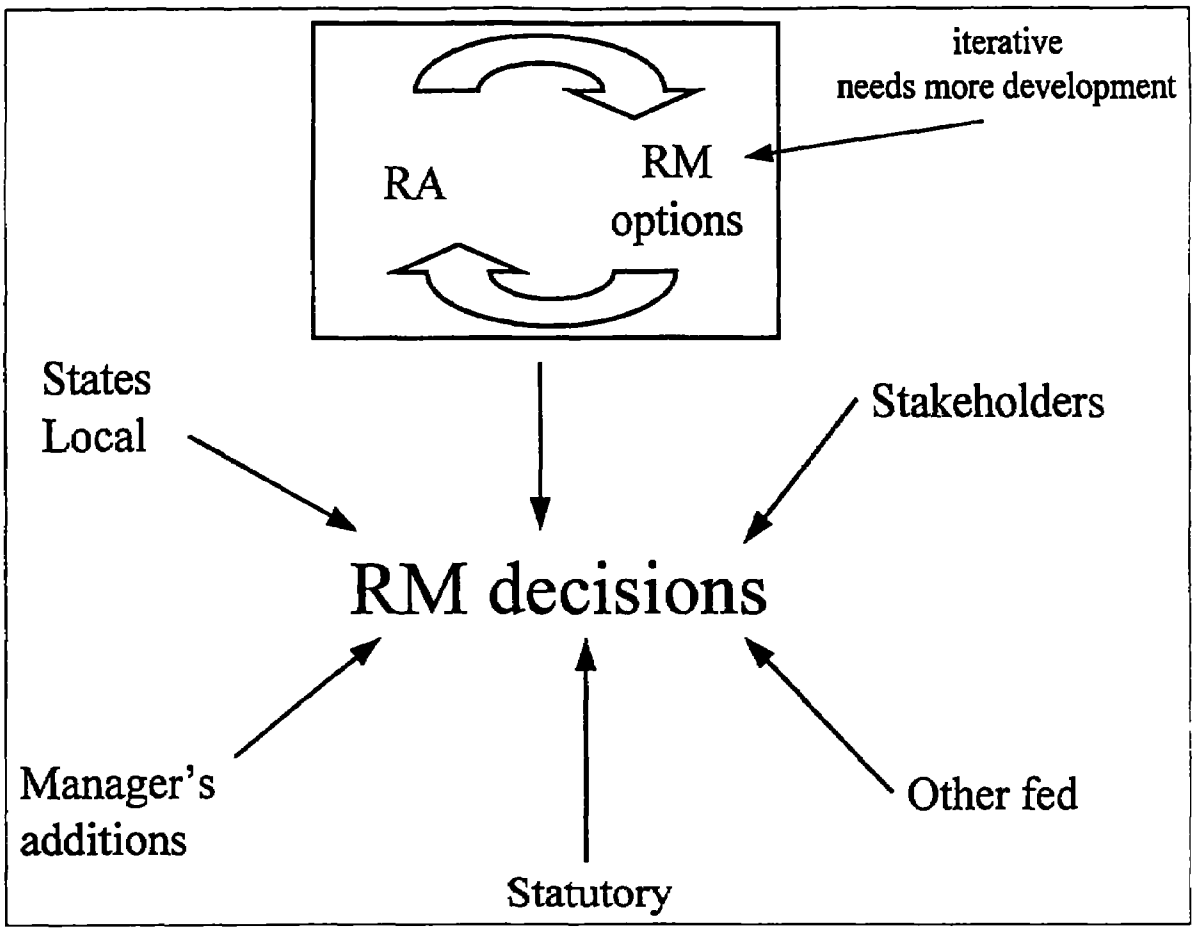


Exhibit 1 - Breakout Group 3 Comprehensive Model

- Risk management is the primary reason EPA exists as an Agency.

Breakout Group 4

This group's discussion centered on the intended purposes of the five models presented in Appendix D: the "olive cell" model, the "master card" or "egg" model, the National Research Council model, the Science Advisory Board model, and the model created by the Presidential/ Congressional Commission on Risk Assessment and Risk Management.

As they reviewed the handout, the group suggested that the word "paradigm" not be used in the future. Individuals presented a series of other observations. There was consensus that all the models were useful; to some degree, all models described the relationship between risk assessment and risk management. All models were seen as linear in nature. Several observations were made that linearity may not be very useful, either for presenting information or for representing how the risk-management process actually takes place. In reality, it was observed that there is more action of an iterative and parallel nature. This continued to be a main aspect of the group's critique of the models. In addition, the group wondered if one model could be sufficiently versatile to handle the variety of environmental issues that might be addressed.

Group 4 noted that there should be an awareness of the possible statutory constraints of the use of models. Also, the options listed in the models were viewed as sufficient in number, but

lacking in any information on their relative strengths or weaknesses. In addition, options need to be resource-based. And, with the exception of the 1996 NRC model, the models are deficient in defining input into the various options. The group also felt it was important to highlight continually the importance of stakeholder involvement, while making it clear that the nature and involvement of stakeholders should vary from step to step.

The group discussed the various purposes of the models. They questioned how a model can guide research or be used to educate the public. Again, doubt was expressed that a single model could incorporate all approaches reflected in the five models examined. Members of the group observed that a model is helpful in allowing users to pick and choose which elements might be appropriate given their specific issues. Several purposes of the model were suggested:

- The model could serve as a guide to risk managers in program offices
- The model could be used within ORD to serve as a reminder of factors that may not be obvious

The group also wondered whether the model should help ORD define research needs or should ORD respond to the needs of the program offices using the model. The group proposed a series of questions concerning the purpose of risk-management models:

- Is it (the model) useful for program and regional offices in conducting their work?
- If it is useful, is it useful to ORD in assisting program and regional offices?
- Will the model indicate new types of research for ORD?
- Will the model be useful for public discourse (e.g., communicating risk-management decisions to the public)?
- Will the model help influence the way risk management is conducted?

The group believed that the following conditions were applicable to responding to the above questions:

- To respond affirmatively to the second and third questions, one needs to be able to respond similarly to the first
- One can answer "yes" to the first question if the model is seen as a checklist
- One can also answer yes to the first question if the model is seen a guide to stakeholder involvement

Discussion turned to whether the models were lacking in any area. One group member felt that the models were not lacking in any particular aspect, but that their value in communicating risk management to the regions should be recognized. Some felt that the models were lacking in an evaluation stage, in terms of success or performance metrics. This was considered particularly important, since showing tangible risk reduction benefits is a major part of the risk-management

process, but also the most troublesome. The group observed that to produce risk-management decisions, one must have results in mind.

The question was asked which models come closest to reality. Some thought the "master card" model was more realistic than the Science Advisory Board model. The "master card" model was also recognized because it highlights the interplay of science/economic/political concerns. Another thought the "olive-cell" model was closer, but that the model should include a feedback/evaluation loop. Earlier in the discussion, the group observed that the "olive cell" model, when compared to the "master card" model, highlights risk assessment as a *subset* of risk management. However, this model should include non-risk assessment factors that are equally important. For example, the suggestion was made that the nucleus of the "olive cell" be replaced with multiple "mitochondria" or "organelles," each denoting additional factors to be considered. Following onto this idea was the suggestion that the model might be best rendered in hypertext, with a basic first page showing the model structure and its associated "organelles." Hypertext links could be provided to pages which describe in detail each of the components. Finally, the group noted that the Presidential Commission model has all of the necessary elements; however, the concept of iteration needs to be added.

The group also pondered the utility of the models to the programs. One discussion participant felt that because economic/political considerations are most important to risk management, the "master card" model is most useful. Observations included that this model was useful as an explicit checklist, so perhaps only a checklist was necessary. Ultimately, the group concluded that the model should be flexible enough to accommodate different environmental issues.

The group closed its discussion with the following cautionary question: "Are we being too EPA-centric?"

In its report to the plenary session, Group 4 highlighted the following points:

- Superfund has developed a model surrogate in practice
- Focus should be placed on the iterative nature of the process
- An alternative to very complex diagrams is a checklist
- A good choice in models might be the 'olive-cell' with additional "organelles"
- Risk assessment is part of a broad risk-management process and does not exist for its own sake
- Defining the problem is paramount
- Evaluation data are missing from some of the models but are very important
- Move towards simplicity: more complexity = less usefulness
- One solution is to add hypertext links to the sub-diagrams for each organelle

The presentation concluded with the following observation: "The fact that this process highlights the complexity of developing management options, while including contributing factors such as laws and prior experience, also highlights research opportunities for ORD."

Plenary Group Discussion

The plenary group discussion after the morning breakout group presentations resulted in the following points about the models:

- Exit strategies are not covered in circular diagrams and would be useful
- Checklists should be suggestive, not prescriptive, to maintain flexibility in application
- Stakeholder perspectives need to be kept in mind at all times, but they need not be intimately involved at every step. The "average Joe's" opinion is contained in the laws in the first place. That is our mandate.
- Linear diagrams are not really useful; we need models with iterative loops and which include an exit strategy
- The "egg" diagram is useful in that it points out that risk assessment is part of the entire risk-management process. This diagram also specifies problem definition.
- Inputs are not well characterized in any diagram and models are lacking in evaluation functions
- Models lack a component of concern about residual pollution and cross-media concerns
- Models do not help us to define areas of research or include information about what has or has not worked previously. Evaluation of results would be a good ORD area – maybe a focus on anecdotal as well as theoretical research.

4.2 Case Study Presentations - Information Used to Inform Risk-Management Decisions

Case study presentations discussed the kinds of information used to make risk-management decisions during particular projects. Case studies addressed the following questions:

- What kinds of non-risk assessment information (e.g. economic; science, other than hazard and exposure data; technological feasibility; environmental justice) did your program consider when making a risk-management decision?
- How did such information factor into the decision-making process?
- How did your program obtain this information?
- Did statutory mandates encourage or limit the consideration of such information? If so, how?
- What uncertainties on the risk-management side were dealt with?

- What further information would have been valuable to inform your program's decisions?

Case studies and ensuing group discussions are summarized below.

4.2.1 Al/Mg Phosphide Case Study (Mark Hartman - OPP)

Phosphide gas is a fumigant, often used to kill mammals and insects infesting agricultural facilities and other storage areas. The primary method of use is to seal a facility, activate the phosphide gas, and then aerate the building. Phosphide is registered under FIFRA, which requires a cost-benefit analysis. The objective of control is to ensure that pesticides do not present unreasonable adverse effects (risks) to humans and the environment. Re-registration involves data collection and risk assessors use this information as the basis for risk-management decisions, which are called Registration Eligibility Decisions, or REDs.

Risk assessment factors considered include toxicology, exposure rates, Agency policies and guidelines, and scientifically-derived risk estimates. Risks are determined for workers, bystanders, and endangered species. In this assessment, risks were not estimated for dietary or drinking water exposures. Non-risk assessment information considered included incident information such as fatality incidents, economic benefits of avoiding pest damage by using phosphide fumigants, and technological availability of alternative methods, such as use of methyl bromide. The role of cost in alternative selection is not necessarily primary, but the weight given it depends on the strength of other factors. Information comes from government agencies, the National Pesticides and Toxics Network, and State databases. Uncertainties associated with risk assessment include the duration of exposure versus toxic effects, the potential for exposure in open air, and uncertainties associated with alternative analysis and technological feasibility. Some information about alternative technologies exists; however, ORD research in this area would be helpful.

An ideal set of information for risk management decision-making would include:

- Highly refined scientific information on exposure in the "real world"
- Clear understanding of the human-to-animal relationship
- Comprehensive incident reporting and analyses
- Verifiable damage estimates
- Reliable understanding of the effectiveness of alternatives to phosphide use
- Efficient lines of communication about alternative technologies
- Detailed economics profiles

4.2.2 ODP Chemical Removal and Replacement – Case Study for Stratospheric Ozone (William Rhodes - OAR)

With the 1974 stratospheric ozone depletion announcement by Rowland and Molina, the public began to stop buying Chlorofluorocarbon (CFC) containing products. Despite this action, the measurable impacts of CFCs continued to increase. Motivated by a suit by the National Resources Defense Council, EPA, under Administrator Lee Thomas, concluded that it needed to act on this issue before all evidence was collected to avoid letting today's risks become tomorrow's crisis.

Risk assessment began and stratospheric impact studies and assessment and biological and climatic effect research were performed beginning in 1974 and continuing the 1980s. Industry reacted by stating that it was "innocent until proven guilty" and equating the rights of people with the rights of chemicals. In 1978, the use of CFCs as a propellant was banned except in cases in which no alternatives were possible and the product was considered essential.

Risk management took many forms during this initiative. EPA hired the Rand Corporation for technology support. A source characterization of chemicals and sources with detailed reports was performed. Control options such as alternative selection and replacement chemicals were evaluated for their potential across industries, by control per chemical, and by considering end-of-pipe versus alternative technology or treatment methods. Cost and benefit analyses were performed. However, industry argued that the theorized depletions could not be happening and posited that bans on CFCs would adversely affect worker safety and the economy of the nation.

Further scientific evidence and details about the effects of CFCs, such as the enlarging hole in the ozone layer, led to an increase in control efforts on a multinational level. The result was the 1986 Regulatory Impact Analysis. Ultimately, CFC control efforts were organized in a multinational plan based on agreement reached in the Montreal Protocol. Industry continued to resist, with the exception of the electronics and solvents industry. Through 1988 and 1989, EPA research resulted in identifying viable process chemical substitutes that refuted industry's assertion that no substitutes were available.

Risk management moved to a new level as a result of these available alternatives. The chemical industry renewed research efforts. EPA continued to prove the cost and process viability of substitutes. Most risk-management action in the 1990s involves further understanding of human and biological system effects, research to find ways to lessen impacts through prevention and adaptations, and continued research about rapid mitigation technologies.

Several principles emerged from this multi-phased and multinational effort. First, scientific data gathering and risk management are best performed in an atmosphere of freedom that promotes factual conclusions as opposed to political or qualitative conclusions. Politics works best after the facts are known. Second, industry needs to be involved. While the interests of industry are usually about short-term financial considerations, the attitudes and roles of industry evolve during this process. While first objecting to the very fact that CFCs were suspected of causing atmospheric harm, industry has now identified and switched over to safer substitutes under the motivation of various drivers, such as public opinion and EPA research. Third, ORD and program offices can benefit from working together in situations in which ORD allows program offices to define their needs and then is able to meet those needs.

Group discussion focused on the issue of continuing CFC use in developing countries. Because of the economics of CFC elimination and substitution in developing countries, the Montreal Protocol built in a longer time frame for CFC reductions in poorer economies. The phase-out has not been followed, but there is little official resistance. The primary problem is the black market and the fact that China is not a signatory of the Protocol. Ongoing research includes active study of the effects of alternatives, including potential future problems presented by the CFC substitutes themselves.

4.2.3 Valley Wood Preserving Superfund Site (Patricia Erickson - ORD)

The Valley Wood Preserving Superfund site was historically used as a wood pressure treating facility. The site was brought to the attention of the California Department of Environmental Quality (DEQ) by site, neighbors who complained of foul-looking ponded water at the site and were concerned about effects on their water wells. The site was added to the Superfund list in 1989 and is in an area of mixed residential and agricultural use. Both California and Superfund have certain standards to be used as starting points for determining the cleanup goals for the site.

This site presented a variety of challenges since it could be considered a model of how not to construct and operate a pressure treating operation. The pole barn, where wood was dried, and chemical storage tanks were located on the edge of the site, thus allowing spills to run off-site. Paved areas were completed after preserving chemical had already inundated site soils. The site had been cited for operating over five years without a permit from the local water quality authority. California state authorities had worked with the facility and identified chromium in site monitoring wells. Information gathering at this site was done more easily than at others because it is a relatively small site. Consequently, the Record of Decision was signed quickly in 1991. Risk management decision-making at the site was performed according to the established Superfund process, given in Section 2.1.6.

Characterization activity first involved a site assessment; chromium and arsenic contamination was found at the surface, in subsurface soils, and in the ground water. The decision was made to use an innovative, in situ groundwater treatment and to perform a reduction in the mobility of water toxics. Long-term effects were an issue at this site because inorganics cannot be transmuted. Cost was not a deciding factor in terms of comparative treatment costs, unless it would be extremely high or if the levels of uncertainty associated with projected expenditures were very high. State and community acceptance was easily attained due to previous work performed and the desire of the community to have the site cleaned. Legal considerations involved the difficulty of getting the perpetrator to pay. In this case, the perpetrator indicated willingness to pay but threatened bankruptcy and had to be ordered by the Court to act.

The establishment of soil cleanup standards was a technical issue that affected risk management decision-making. Leaching standards assume high attenuation and the levels for arsenic had to be established by considering direct contact versus background levels. The groundwater had to be treated in concert with California's non-degradation policy and the technology chosen was an innovative treatment technique.

4.2.4 Mid-Atlantic Integrated Assessment Case Study (Tom Demoss - Region 3)

The Mid-Atlantic Integrated Assessment (MAIA) is a development effort that will result in a model ecosystem program for the Mid-Atlantic region, including all of Region 3 and parts of Regions 2 and 4. Pennsylvania, Maryland, Delaware, Virginia and West Virginia, and the District of Columbia are covered in their entirety. Parts of New Jersey, New York and North Carolina are also covered. Because of dense population, proximity to Washington, DC, and association with studies performed to assess the Chesapeake Bay, this program has a great deal of data.

Special care has been taken to design the software for the project so that the data presented are usable by a variety of audiences. The resulting software is a very user-friendly program with highly detailed assessable graphic presentations of assessment data. The graphics use color and other design features to present data in the most accessible formats possible.

The MAIA mission is to provide integrated scientific knowledge to support the environmental decision-making process for the Mid-Atlantic region. Goals in support of this mission include:

- Develop acceptable and valid environmental indicators for natural resource protection
- Merge physical, chemical and socioeconomic data into dynamic and useful assessments
- Develop the best characterizations of environmental resources to data
- Have data influence and drive management decisions and influence public perception and opinion
- Translate data to relative risk

Work on the MAIA has been performed in concert with ORD and stakeholders. Satellite surveys are being utilized to characterize some areas, and field studies are being performed to augment this data since this technology has limited accuracy with regard to wetlands. The reports that will be available by 2001 include information on:

- Mid-Atlantic landscape atlas – a landscape cluster analysis where landscapes will be ranked according to 33 criteria
- A report on the condition of Mid-Atlantic estuaries, which is being done through field data collection
- Pesticides in Mid-Atlantic ground water
- State of the streams in highland areas using benthic index and onsite water data to quantify water quality
- State of the forests
- State of agriculture
- Condition of biodiversity

The study will also result in an atlas detailing environmental stresses, loading to watersheds, and other conditions, such as impervious areas, that have an effect on streams. Socioeconomic considerations will also be given to answer questions about what drives the land use changes in the areas assessed.

The MAIA assessment framework is divided into levels - each level integrates and expands on data from the previous level. Level one considers individual systems such as forests and streams; level two explores the relationships within resource groups; and level three is concerned with integration and associations between resource groups, such as streams and forests.

Group discussion following the case study presentation focused on the usability of the MAIA program by decision makers with varying degrees of expertise. How, for example, can the program explain the problem of nitrates in water? MAIA can demonstrate the biological impacts and then explain the causes. To validate usability, program designers will keep testing out ideas with focus groups and State users. Short fact sheets are also a product of this effort, and program staff is also working with other groups, such as the Bay Alliance, to provide information.

A participant suggested that one result of this effort might be an actual EPA-led project demonstration, on a topic such as habitat restoration. This kind of high-profile, EPA-sponsored activity might help the Agency gain support and trust out in the Regions.

4.3 Evaluating the Paradigms, Part Two

The afternoon breakout groups were instructed to look again at the models and the general risk-management process with the addition of the four case studies presented. The groups structured their work around the following questions:

- Did any case study describe a process or provide information different than the discussions and conclusions drawn from the modeling presentations?
- Did EPA, industry, or someone else develop the risk-management options?
- Should EPA actively develop risk-management options?
- Can industry be forced to reduce the market for their product?

For example, in the stratospheric ozone case study presented, the risk management and risk-assessment processes were reversed. Based on the potential for further damage caused by CFC use, EPA made the decision to move forward with risk-management decisions and their implementation, letting the risk assessments catch up.

The breakout groups again prepared informal reports that were presented to the plenary group and which answered the discussion questions. Notes from the breakout groups' work were captured on flip charts, which are transcribed in Appendix E. Breakout group reports are summarized below.

4.3.1 Reports from the Break-Out Groups, Part Two

Breakout Group 1

This breakout group was not monitored by a recorder. However, their report to the plenary group is summarized.

The risk-assessment process is well defined, while that of risk management is less understood. The models developed to date all have applications, although the concrete steps necessary for risk management are not necessarily clear. Uncertainties are a problem in risk management, in that the data necessary to resolve them requires expenditure of considerable resources. In reality, EPA often makes many decisions without the benefit of the time or resources to follow all the steps in a complex model. Actions are decided along a continuum of complexity, between a gut feeling of what is necessary to a full investigation at the level of the Science Advisory Board, based on the problem at hand and the mechanism that triggered the risk action in the first place. In some cases, the use of these full models may make decision-making unnecessarily complex. Finally, the models do not necessarily account for the differences in risk management of human health issues as opposed to ecological risks.

Breakout Group 2

Generalizing from the case studies presented, the group articulated that the type of risk encountered in the assessment phase is the driver of the information needed to make risk-management decisions. For example, risks that are acute versus chronic, or immediate versus long-term, or limited in scope versus broad-based, require very different management tools. Risk managers may prioritize based on the type and extent of the risk. This process is sometimes called risk tiering.

The Valley Wood case study demonstrated the use of the Superfund model, which takes a more iterative approach to risk management. Decisions about remedies, such as removal versus in situ remediation, were made according to the nine Superfund criteria described in Section 4.2.3. Before beginning the risk assessment, management goals and public concerns were identified, to the extent possible.

The types of information needed are also driven by the nature of the entity making risk-management decisions. EPA, other Agencies, and public/individuals have different goals. This means that communication between project teams and all stakeholders is very important. Any model must work for decision-makers outside of EPA, as well as for Agency risk managers. The use of several case studies linked with the models might be a good way to demonstrate use of the model.

The models all need to take into account some methods of verification and validation of decisions – did the risk-management decisions made achieve the Agency's intended goals? There must be a process to connect outcomes to actions.

Breakout Group 2 summarized their afternoon work session in these points:

- It is necessary to identify management goals and public concerns
- The types of risk drive the type of information needed. Risk tiering may be necessary
- Identify the decision-maker
- Evaluate available technological alternatives
- Apply an iterative approach, e.g., the nine criteria of the Superfund program
- Include measures of success to evaluate whether the goals have been achieved

Breakout Group 3

Breakout Group 3 structured its work around each individual case study.

Mid-Atlantic Integrated Assessment Case Study

MAIA involves more strategic thinking about risk management. This model could possibly be used as a tool for the risk manager to identify areas for future work. The group felt that the model only focused on the water issue as an indicator of regional environmental status. A risk-management model should include other media as well.

EPA Region 3 has spent significant resources on communicating risk to the community in an attempt to gain acceptance of its risk-management decisions. The work done by Region 3 helps prioritize risks and identify problems in a way stakeholders can understand.

CFC Presentation Case Study

The CFC presentation outlined a decision in which a detailed risk assessment was not required to propose action. This may represent an anomaly, in which the limited risk assessment suggested overwhelming benefits to taking immediate action. Waiting to collect more data could have led to tragic results.

Valley Wood Superfund Site Case Study

The Superfund site example was a problem that had already occurred and EPA was trying to mitigate the situation. The example was very structured and was requirement-oriented because of the regulations governing the Superfund program. The site followed a linear process in risk management decision-making, which might not be a model for all situations.

Phosphide Fumigants Case Study

Breakout Group 3 suggested that the risk-management model should not be prescriptive. Instead, it should be iterative, flexible, and able to consider site-specific characteristics. An encompassing risk-management model should consider the difficulties in balancing the cost-benefit equation and the possibility of standardizing cost-benefit determinations across programs.

To improve the risk-management process, the group suggested that risk management should be an open and iterative process providing for input from stakeholders, as well as communication of risk-management options to stakeholders and decision-makers. Risk-management projects might include an independent auditor to make an unbiased final decision as an alternative to obtaining consensus from all stakeholders.

To improve information for risk management, the group suggested that transaction costs are important and need to be considered as part of risk management. The risk-management process is complicated and this workshop is an early step in describing the process, the range of risk-management projects, and the possible decisions resulting from risk-management activities. There is a need for an "institute" to provide information on risk management and fill in data gaps. The existence of such an institute will help make the models discussed at this workshop viable

Breakout Group 4

Group 4 began its discussion by outlining what it considered to be the benefits of well-done case studies. Such studies:

- Document examples of successful and unsuccessful approaches/actions and order/characterize examples
- Provide an historical perspective
- Provide a feel for the diversity of issues
- Can be used to create a model based on actual cases

The group suggested that, given these benefits, it might be useful to use a contractor to perform ORD-directed research about how the process actually works in the program and Regional offices.

The group used this as a launching point for its discussion centering around the relationship between ORD and the program and Regional offices. A variety of aspects to this relationship were addressed by the group, including issues of communication, timing of involvement, current ORD contributions, possible new areas for contribution, and practical and theoretical considerations.

The group noted that decision-making is often a matter of managing constraints. At times, it is difficult to incorporate risk assessment into risk management during the decision-making process. However, the uncertainty in risk assessment must be dealt with, particularly in terms of uncertainty or safety factors. ORD may disagree with the risk-management approach taken by the program offices. Hence, the program and regional offices may object to ORD involvement and could feel a lack of trust. For instance, one reason program or regional offices might object to ORD involvement is that the office has a history of last-minute interruptions to the decision-making process on the basis of "new science." While this may be true, it may also be related to the fact that ORD's contributions are coming to the table late in the process. This discussion touched upon the broader issue of inter- vs. intra-agency involvement.

The group noted that programs want to keep decision-making within their purview, but that ORD should provide technical support to that process. It was recognized that traditional support is still needed, but that the Agency is dealing with more issues, such as stakeholder involvement, and that ORD might have a role in helping the program offices address them. ORD's assistance to the Superfund offices was discussed. ORD helps in the evaluation of remedial options, but the program retains the final choice. In part, this is because the program office takes the responsibility for the decisions and performs the non-science aspects of the evaluation stages. In practice, program offices often become mediator between our (ORD's) and their (industry's) science. Thus, some sense of separation between the offices is necessary.

There was consensus that early involvement is the key to any possible value-added ORD involvement. The group noted that early ORD involvement might result in new risk-management options based on an understanding of a broader range of possible technologies.

The group returned to a discussion of the models and considered items on the "checklist" or in the "models" on which program offices need input and to which ORD might be able to respond. Group discussion focused on the following questions: Are there areas of the models that have gone unfilled? Can ORD provide research support to fill in the blanks? There was agreement that ORD's resources of technical knowledge could help guide the development of efficient/better regulatory guidance. This would require including ORD as part of the thinking process; again, early involvement is the key. The focus of the discussion shifted to the concept of incorporating prevention strategies in the options identification stage of risk management. It was noted that prevention is not reflected in the models. The discussion of prevention was lengthy, and the group considered it to be an area in which ORD could make a large contribution if brought into the process early.

Other identified areas for ORD support were:

- Research on the multi-party bargaining process
- Development of tools to help evaluate cost and effectiveness issues and to determine what risk-management strategies are appropriate in which cases
- Research on the identification of appropriate application of market-based regulatory strategies
- Research on methods of communicating uncertainties

A number of theoretical observations were presented throughout the discussion. One way to view risk management decision-making across the variety of individual applications is that in each case one needs to deal with "constraint management." Risk managers navigate the differences between a scientific community and a litigious society. The scientific community, while often in disagreement, usually works "to narrow the bounds of what is true." On the other hand, a litigious society works to widen the space between what is true and what is not, pushing attention to the outer margins of this space. The group thought risk assessors took a reductionist approach: they consider a range of inputs or factors which lead them to conclude a certain output. Risk managers often attempt to include an inductive approach in their deliberations.

Group 4 maintained an awareness of outside implications for risk management and raised concerns throughout the discussion. One concern was articulated as, "what is the real reason for the risk-management decisions made?" This highlighted the fact that while ORD may look to provide additional support, often the risk assessment and technical or scientific input must be balanced with political or other unrecognized factors.

The group also considered that the practicability of increases in intra-agency participation should be understood before attempting to implement new processes. Group 4 concluded that, as an agency, EPA needs both to make the regulations and actions understandable to those involved, and to understand them internally before releasing them to the public.

The report to the Plenary session stressed the following points and raised some important questions:

- ORD could take steps to understand and flesh out the risk-management process. The office could do this by:
  - Developing more case studies of risk-management decisions.
  - Working more closely with the program and regional offices in the decision-making process.

- Where should ORD scientists in general be involved in the risk-management process?

- Pollution prevention is not adequately represented in the frameworks:
  - The frameworks work well for large, well-recognized problems.
  - They do not allow for looking at pollution prevention options as new management processes are developed. Is this an area which should be handled by industry or should ORD have a role in conducting applicable research?

- What are some newer, key areas in which ORD could contribute through research to the present risk-management process:
  - Cost and effectiveness issues.
  - Evaluations of overall program effectiveness.
  - Negotiation process.
  - Communicating risk-management options.
  - Market-based systems.

5. Wrap-Up Activities

5.1 Summary of Issues and Action Items (Hugh McKinnon - ORD)

Risk assessment was not the focus of this workshop intentionally, in order to allow the group to focus on other influences on the risk-management process. The next step is to carry this information into the evolving dialogue at ORD. Many of the comments heard in this workshop are similar to what ORD has been hearing in stakeholder meetings for reinvention plans.

Feedback includes suggestions that ORD must do a better job in: (1) researching science and technology issues, e.g., impacts to ecosystems; (2) defining the implications of scientific research; and (3) effectively communicating these implications to risk managers. Information must be presented simply so that all stakeholders can understand it and make informed decisions. Any model or models developed should not be tightly prescriptive. Risk managers need guidance, such as checklists, but any guidance should incorporate flexibility.

The risk-management process would benefit from having more guidance about how to conduct a public process in ways that are fair, lawful, cost-effective, and fit community values. ORD might want to consider adding expertise so that research can be most effective. The goal is not to decrease science support but to add capacity to address social and economic issues at greater depth.

Because risk management is an iterative process with many different points, two-dimensional models have difficulty in portraying it correctly. Comprehensive models must be designed to incorporate the iterative nature of risk management.

Several major themes emerged from the workshop:

- The information needed for risk management is risk-driven and project-specific.
- Roles of all project participants and stakeholders, especially the roles of risk manager and risk assessor, need to be defined at project conception.
- Communication between the risk assessor and the risk manager during a project should be iterative and ongoing.
- Risk-management models need to be flexible, simple, clear, and include problem prioritization considerations.
- To provide comprehensive information to inform risk-management decisions, EPA needs to improve the depth of the decision makers' understanding through intensified research on science and technology issues.
- Information about innovative technologies that might be available must be communicated to risk managers.
- It might be necessary to acquire additional expertise to gather information about social and economic issues influencing risk management.

- There is a need to enhance communication paths both across EPA offices and among project members.

Perhaps the most important finding from this workshop is that open communication throughout the risk management decision-making process is key to its success.

5.2 Preview of Next Workshop

The Office of Science Policy will sponsor a second workshop in the Risk Management series. The next, to be held July 14-15, 1999, will focus on communication and stakeholder involvement in the risk-management process. The scope of the final workshop in the series, to be held late this summer or in the Fall, is currently being defined. Organizers want this workshop to build in some way on the concepts developed through previous workshops. Workshop participants are invited to forward suggestions about the content of this final workshop.

The objectives of the July workshop on communication and stakeholder involvement in the risk-management process are to discuss risk assessor and risk manager communications and how this communication should inform the decision-making process. Additionally, stakeholder involvement in decision-making will be explored. Finally, the extent to which current models of the risk-management process accommodate risk assessor and risk manager communication and stakeholder involvement will be discussed.

APPENDICES

Appendix A. List of Participants

Washington, DC
June 15-16, 1999

Bill Anderson
EPA OW/OST/EAD
401 M Street, SW (4303)
Washington, DC 20460
tel. 202-260-5131
fax 202-260-7185
anderson.william@epa.gov

Dr. James K. Andreasen
EPA ORD/NCEA
401 M Street, SW (8623D)
Washington, DC 20460
tel. 202-564-3293
fax 202-565-0076
andreasen.james@epa.gov

Andrew P. Avel
EPA ORD/NRMRL/ALD Pest.& Toxics
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7951
fax 513-569-7680
avel.andy@epa.gov

Ben Blaney
EPA ORD/NRMRL
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7852
fax 513-569-7680
blaney.ben@epa.gov

Kathryn Boyle
EPA OPPTS/OPP/SRRD/SRB
401 M St., SW (7508C)
Washington, DC 20460
tel. 703-305-6304
fax 703-308-8005
boyle.kathryn@epa.gov

Phil Budig
EPA OPPTS/OPP/SRRD
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8029
fax 703-308-8041
budig.phil@epa.gov

Amy Caicedo
EPA OPPTS/OPP/SRRD
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-9399
fax 703-308-8041
caicedo.amy@epa.gov

Kathleen Conway
EPA OA/SAB
401 M Street, SW (1400)
Washington, DC 20460
tel. 202-260-2558
fax 202-260-7118
conway.kathleen@epa.gov

David Cooper
EPA OSWER/OERR
401 M Street, SW (5204G)
Washington, DC 20460
tel. 703-603-8763
fax 703-603-9100
cooper.david@epa.gov

Elizabeth Cotsworth (speaker)
EPA OSWER/OSW
401 M Street, SW (5301W)
Washington, DC 20460
tel. 703-308-8895
fax 703-308-0513
cotsworth.elizabeth@epa.gov

Kerry Dearfield
EPA OSP/ORD
401 M Street, SW (8104R)

Washington, DC 20460
tel. 202-564-6486
fax 202-565-2925
dearfield.kerry@epa.gov

Tom Demoss
EPA Region 3, Environmental Science Center (3ES01)
701 Mapes Road
Ft. Meade, MD 20755-5350
tel. 410-305-2739
fax 410-305-3095
emoss.tom@epa.gov

Karen Doerschug
EPA Design for the Environment
401 M Street, SW (7406)
Washington, DC 20460
tel. 202-260-0695
fax 202-260-0981
doerschug.karen@epa.gov

Patricia Erickson (speaker)
EPA ORD/NRMRL
26 W. Martin Luther King Drive
MD 235
Cincinnati, OH 45268
tel. 513-569-7406
fax 513-569-7680
erickson.patricia@epa.gov

Robbi Farrell
EPA OPPT/OPP/Special Review & Reregistration Branch
401 M Street, SW (7508C)
Washington DC 20460
tel. 202-308-8065
fax 202-260-1847
farrell.roberta@epa.gov

Jerry Filbin
EPA OA/OR
401 M Street, SW (2184)
Washington, DC 20460
tel. 202-260-8099
fax 202-260-7875
filbin.gerald@epa.gov

Demson Fuller
EPA OPPTS/OPP
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8062
fax 703-308-7042
fuller.demson@epa.gov

Peter Grevatt
EPA OSWER
401 M Street, SW (5105)
Washington, DC 20460
tel. 202-260-3100
fax 202-401-1496
grevatt.peter@epa.gov

Ed Hanlon
EPA ORD/OSP
401 M Street, SW (8104R)
Washington, DC 20460
tel. 202-564-6761
fax 202-565-2911hanlon.edward@epa.gov

Mark Hartman (speaker)
EPA OPPTS/OPP
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-0734
fax 703-308-7042
hartman.mark@epa.gov

Scott Hedges
EPA NRMRL/ORD
401 M Street, SW (8301D)
Washington, DC 20460
tel. 202-564-3318
fax 202-565-0075
hedges.scott@epa.gov

Jonathan G. Herrmann

EPA ORD/NRMRL
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7839
fax 513-569-7680
herrmann.jonathan@epa.gov

Brian Hirsch
EPA OIA/OTCA
401 M Street, SW (2670R)
Washington, DC 20460
tel. 202-564-1138
fax 202-565-2411
hirsch.brian@epa.gov

Stephen C. James
EPA ORD/NRMRL
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7877
fax 513-569-7680
james.steve@epa.gov

Joan Karrie
EPA OPP/IRSD
401 M St., SW (7502C)
Washington, DC 20460
tel. 703-305-5289
fax 703-305-5512
karrie.joan@epa.gov

Timothy Kropp
EPA OSWER
401 M Street, SW (5103)
Washington, DC 20460
tel. 202-260-1270
fax 202-401-1496
kropp.timothy@epa.gov

Arnold Kuzmack
EPA OW/OST
401 M Street, SW (4301)
Washington, DC 20460
tel. 202-260-5821
fax 202-260-5394
kuzmack.arnold@epa.gov

Rashmi Lal
EPA CEIS
401 M Street, SW (2152)
Washington, DC 20460
tel. 202-260-3007
fax 202-260-4968
lal.rashmi@epa.gov

Stanley Laskowski (speaker)
EPA Region 3
1650 Arch Street
Philadelphia, PA 19106
tel. 215-814-2989
fax 215-814-2782 or
215-814-2783
laskowski.stanley@epa.gov

Robert Lee
EPA OPPTS/OPPT
401 M Street, SW (7406)
Washington, DC 20460
tel. 202-260-1670
fax 202-260-0981
lee.robert@epa.gov

Kimberly Lowe
EPA OPPTS/OPP/SRRD/SRB
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8059
fax 703-308-8041
lowe.kimberly@epamail.epa.gov

Alec McBride

EPA Office of Solid Waste

401 M Street, SW (5307W)
Washington, DC 20460
tel. 703-308-0466
fax 703-308-0511
mcbride.alexander@epa.gov

Douglas McKinney
EPA IEMB/APPCD
MD-60
Research Triangle Park, NC 27711
tel. 919-541-3006
fax 919-541-5227
mckinney.douglas@epa.gov

Hugh McKinnon (speaker)
Acting DAA for Science, EPA ORD
401 M Street, SW (8101R)
Washington, DC 20460
tel. 202-564-6620
fax 202-565-2910
mckinnon-HQ.hugh@epa.gov

John Meagher
EPA OW/OWOW
401 M Street, SW (4502F)
Washington, DC 20460
tel. 202-260-1917
fax 202-260-2356
meagher.john@epa.gov

Cletis Mixon
EPA OPPTS/OPP/SRRD
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8032
fax 703-308-8005
mixon.cletis@epa.gov

Dean Monos
EPA OPPTS/OPP/SRRD/RB3
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8074
fax 703-308-8005
monos.dean@epa.gov

M. Granger Morgan (speaker)
Carnegie Mellon University
Dept. of Engineering and Public Policy
Pittsburgh, PA 15213
tel. 412-268-2672
fax 412-268-3757
granger.morgan@andrew.cmu.edu
gm5d+@andrew.cmu.edu

Jeff Morris (speaker)
EPA ORD/OSP
401 M Street, SW (8104R)
Washington, DC 20460
tel. 202-564-6756
fax 202-565-2926
morris.jeff@epa.gov

Marcia Mulkey (speaker)
Director, EPA Office of Pesticide Programs
401 M Street, SW (7501C)
Washington, DC 20460
tel. 703-305-7090
fax 703-308-4776
mulkey.marcia@epa.gov

Lee Mulkey (speaker)
EPA ORD/NRMRL
26 W. Martin Luther King Drive (MC 235)
Cincinnati, OH 45268
tel. 513-569-7689
fax 513-569-7549
mulkey.lee@epa.gov

Gary Mullins
EPA OPPTS/OPP/FRR
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8044
fax 703-308-8005
mullins.gary@epa.gov

Deirdre L. Murphy, Ph.D.
EPA OAR/OAQPS, Risk & Exposure Group
MD-13
Research Triangle Park, NC 27711
tel. 919-541-0729
fax 919-541-0237
murphy.deirdre@epa.gov

Dan Murray

EPA ORD/NRMRL/TTSD
26 Martin Luther King Drive
MD-G75
Cincinnati, OH 45268
tel. 513-569-7522
fax 513-569-7585
murray.dan@epa.gov

Michael Nieves
EPA OPPTS/OPP/SRRD/RB1
401 M Street, SW (7510W)
Washington, DC 20460
tel. 703-308-6351
fax 703-308-7042
nieves.michael@epa.gov

Cynthia Nolt
EPA ORD/NCERQA
401 M Street, SW (8723R)
Washington, DC 20460
tel. 202-260-9642
fax 202-260-1812
nolt.cynthia@epa.gov

Barry Nussbaum
EPA CEIS
401 M Street, SW (2152)
Washington, DC 20460
tel. 202-260-1493
fax 202-260-4968
nussbaum.barry@epa.gov

Dan Olson
EPA OW/Office of Ground Water and
Drinking Water
401 M Street, SW (4607)
Washington, DC 20460
tel. 202-260-6269
fax 202-401-6135
olson.daniel@epa.gov

E. Timothy Oppelt (speaker)
EPA ORD/NRMRL
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7418
fax 513-569-7680
oppelt.tim@epa.gov

Phil Oshida
EPA OW/OWOW/Wetlands Division
401 M Street, SW (4502F)
Washington, DC 20460
tel. 202-260-6045
fax 202-260-2356
oshida.phil@epa.gov

Pasky Pascual
EPA ORD
401 M Street, SW (8104R)
Washington, DC 20460
tel. 202-564-2259
fax 202-565-2911
pascual.pasky@epa.gov

Dorothy Patton
Director, EPA ORD/OSP
401 M Street, SW (8104R)
Washington, DC 20460
tel. 202-564-6705
fax 202-565-2911patton.dorothy@epa.gov

Dan Petersen
EPA ORD/NRMRL/TTSD
26 W. Martin Luther King Drive
MD-G75
Cincinnati, OH 45268
tel. 513-569-7896
fax 513-569-7585
petersen.dan@epa.gov

Frank T. Princiotta
EPA IEMB/APPCD
MD-60
Research Triangle Park, NC 27711
tel. 919-541-2821
fax 919-541-5227
princiotta.frank@epa.gov

William Rhodes
EPA OAR/APPCD
86 T.W. Alexander Drive
MD-63
Research Triangle Park, NC 27711
tel. 919-541-4115
fax 919-541-7885
rhodes.bill@epa.gov

Kelly Rimer
EPA OAR/OAQPS
MD-13
Research Triangle Park, NC 27711
tel. 919-541-2962
fax 919-541-0840
rimer.kelly@epa.gov

Deanna Scher
EPA OPP/SRRD/RBI
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-7043
fax 703-308-7042
scher.deanna@epa.gov

Anne Sergeant
EPA ORD/NCEA
401 M Street, SW (8623D)
Washington, DC 20460
tel. 202-564-3249
fax 202-565-0045
sergeant.anne@epa.gov

Victor B. Serveiss
EPA ORD/NCEA
401 M Street, SW (8623-D)
Washington, DC 20460
tel. 202-564-3251
fax 202-565-0078
serveiss.victor@epa.gov

Sally Shaver (speaker)
EPA OAR/OAQPS
MD-13
Research Triangle Park, NC 27711
tel. 919-541-5572
fax 919-541-0840
shaver.sally@epa.gov

Subhas K. Sikdar
EPA ORD/NRMRL/STD
26 W. Martin L. King Drive
MS-497
Cincinnati, OH 45268
tel. 513-569-7528
fax 513-569-7787
sikdar.subhas@epa.gov

Tom Veirs
EPA ORD/NCERQA
401 M Street, SW (8722R)
Washington, DC 20460
tel. 202-564-6831
fax 202-565-2447
veirs.thomas@epa.gov

Mary Ellen Weber
EPA OPPTS/OPPT
401 M Street, SW (7406)
Washington, DC 20460
tel. 202-260-0667
fax 202-260-0981
weber.maryellen@epa.gov

Linda Werrell
EPA OPPTS/OPP/SRRD/SRB
401 M Street, SW (7508C)
Washington, DC 20460
tel. 703-308-8033
fax 703-308-8041
werrell.linda@epa.gov

Jan Young
EPA OSW/EMRAD
401 M Street, SW (5307W)
Washington, DC 20460
tel. 703-308-1568
fax 703-308-0509
young.jan@epa.gov

Hal Zenick (speaker)
EPA ORD/NHEERL
MD-51
Research Triangle Park, NC 27711
tel. 919-541-2283
fax 919-541-4324
zenick.hal@epa.gov

Appendix B. Workshop Agenda

"Identifying Information Needs for Risk Managers" Workshop Series

Information Needs for Risk Management Decision-Making: Toward a Risk-Management Information Model

June 15-16, 1999
Washington Plaza Hotel, Washington, DC

Workshop Objectives

- To identify the types of information (non-risk assessment) that EPA managers need and use to inform their risk-management decisions.
- To conduct a review and analysis of risk-management processes and information needs, for subsequent use in the development of a draft unified model for organizing and providing information to risk managers.

Day 1	**Information Needs, Paradigm Proposals**	
9:00-9:15	Introduction	Tim Oppelt, ORD
9:15-11:30	Panel Discussion-*Media Program Office Information Needs* ▸ Sally Shaver, OAQPS/OAR ▸ Marcia Mulkey, OPP/OPPTS ▸ Elizabeth Cotsworth, OSW/OSWER	
	10:15-10.30 BREAK	
	▸ John Meagher, OWOW/OW ▸ Bill Anderson, OST/OW ▸ David Cooper, OERR/OSWER	
11:30-12:30	LUNCH	
12:30-2:30	Panel Discussion-*Cross-Media and Regional Office Information Needs* ▸ Jerry Phiben, OR ▸ Mary Ellen Weber, OPPT/OPPTS ▸ Stanley Laskowski, Region 3 ▸ Hal Zenick, NHEERL/ORD (Border 2000 project)	
2:30-2:45	BREAK	
2:45-3:25	Presentation-*Evolution of the Risk-Management Paradigm*	Hugh McKinnon and Lee Mulkey, ORD
3:25-3:45	Presentation-*A Few Thoughts on Risk Analysis and Risk Management*	M. Granger Morgan, Carnegie Mellon University
3:45-4:15	Preparation for the Day 2 break-out groups	Jeff Morris, ORD

4:15-4:30	Synopsis of the Day 1 presentations & discussions	Lee Mulkey, ORD
Day 2	**Paradigm Review and Development**	
8:30-8:45	Day 1 Recap; Final Instructions for Break-out Groups	Tim Oppelt, ORD
8:45-10:30	Break-Out Group Exercise–*Evaluating the Paradigms*	
10:30-11:00	Reports from the Break-out Groups	
11:00-2:00	Case Study Presentations–*Information Used to Inform Risk Management Decisions*	
	Phosphide fumigants	Mark Hartman, OPP
	ODP chemical removal and replacement	Bill Rhodes, ORD
12:00-1:00	LUNCH	
	Valley Wood (Superfund)	Patricia Erickson, ORD
	Mid-Atlantic Integrated Assessment (MAIA) case	Tom Demoss, Region 3
2:00-4:00	Break-Out Group Exercise–*Evaluating the Paradigms, Part II*	
4:00-4:30	Reports from the Break-out Groups	
4:30-4:45	Wrap-Up Activities • Summary of Issues • Action Items • Preview of Next Workshop • ADJOURN	Hugh McKinnon, ORD

Appendix C
Guidance to Presenters

A. Guidance for Media Program Office Presenters

EPA Workshop–*Information Needs for Risk Management Decision Making*
First workshop in the series, "Identifying Information Needs for Risk Managers"
June 15-16, Washington Plaza Hotel, Washington, DC

Panel Discussion: *Media Program Office Information Needs*

Guidance for Presenters

When June 15, 1999, 9:15-11:30 a.m.

Where Washington Plaza Hotel, 10 Thomas Circle (14th Street and Massachusetts Ave, NW), Washington, DC

Topic The kinds of information needed to make decisions in [your program office]

Length 15-20 minutes

Format Presentation followed by q&a/discussion. There will be a total of five presentations, with a 15-minute break following the second presentation.

Subject Matter While we expect and encourage each presenter to address the topic from the unique perspectives of their particular program office, there are some key questions that we would like each presentation to address.

- What kinds of information (e.g., economics, science other than hazard and exposure data, technological feasibility, environmental justice) does your program consider when making a decision, taking an action, or implementing a project?
- How is such information factored into the decision-making process?
- How does your program obtain this information?
- Do statutory mandates encourage or limit the consideration of such information. If so, how?
- We are all familiar with the uncertainties inherent in risk assessment. What comparable uncertainties could be reduced in your program's decision-making process if more information were available to decision makers?

- Under ideal circumstances, what information, beyond what is currently available to you, would you consider valuable to inform your program's decisions?

Materials If you would like to have materials photocopied for distribution at the workshop, please send them by interoffice mail or email to Jeff Morris of OSP/ORD by May 28, 1999.

Questions Please call Jeff Morris (202-564-6756) if you have any questions about your presentation, or about other aspects of the workshop series.

Follow-Up Jeff will schedule a conference call with all presenters about a week before the workshop, as a final check-in to answer questions and address any remaining issues.

B. Guidance to Cross-Media Office Presenters

EPA Workshop–*Information Needs for Risk Management Decision Making*
First workshop in the series, "Identifying Information Needs for Risk Managers"
June 15-16, Washington Plaza Hotel, Washington, DC

Panel Discussion: *Cross-Media/Regional Office Information Needs*

Guidance for Presenters

When June 15, 1999, 12:30-2:30 p.m.

Where Washington Plaza Hotel, 10 Thomas Circle (14th Street and Massachusetts Ave, NW), Washington, DC

Topic The kinds of information needed to make, implement, or otherwise address or consider risk management decisions in [your office]

Length 15-20 minutes

Format Presentation followed by q&a/discussion. There will be a total of five presentations.

Subject Matter While we expect and encourage each presenter to address the topic from the unique perspectives of their particular office, there are some key questions that we would like each presentation to address.

- What kinds of non-risk assessment information (e.g., economics, science other than hazard and exposure data, technological feasibility, environmental justice) does your office consider when making, implementing, or addressing/ considering a risk management decision?
- How is such information factored into the decision-making, implementation, or consideration/evaluation process?
- How does your office obtain this information?

- Do statutory mandates encourage or limit the consideration of such information. If so, how?

- We are all familiar with the uncertainties inherent in risk assessment. What comparable uncertainties on the risk management side could be reduced if more information were available to decision makers?

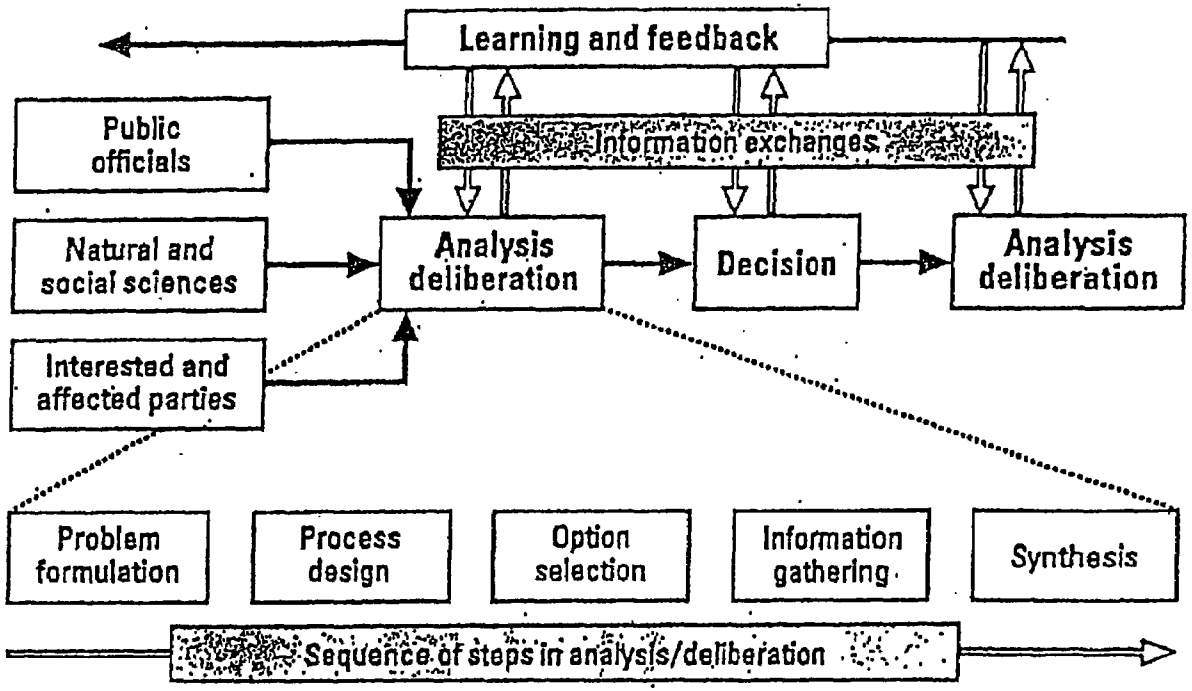
- Under ideal circumstances, what information, beyond what is currently available to you, would you consider valuable to inform your office's decisions?

Materials If you would like to have materials photocopied for distribution at the workshop, please send them by interoffice mail or email to Jeff Morris of OSP/ORD by May 28, 1999.

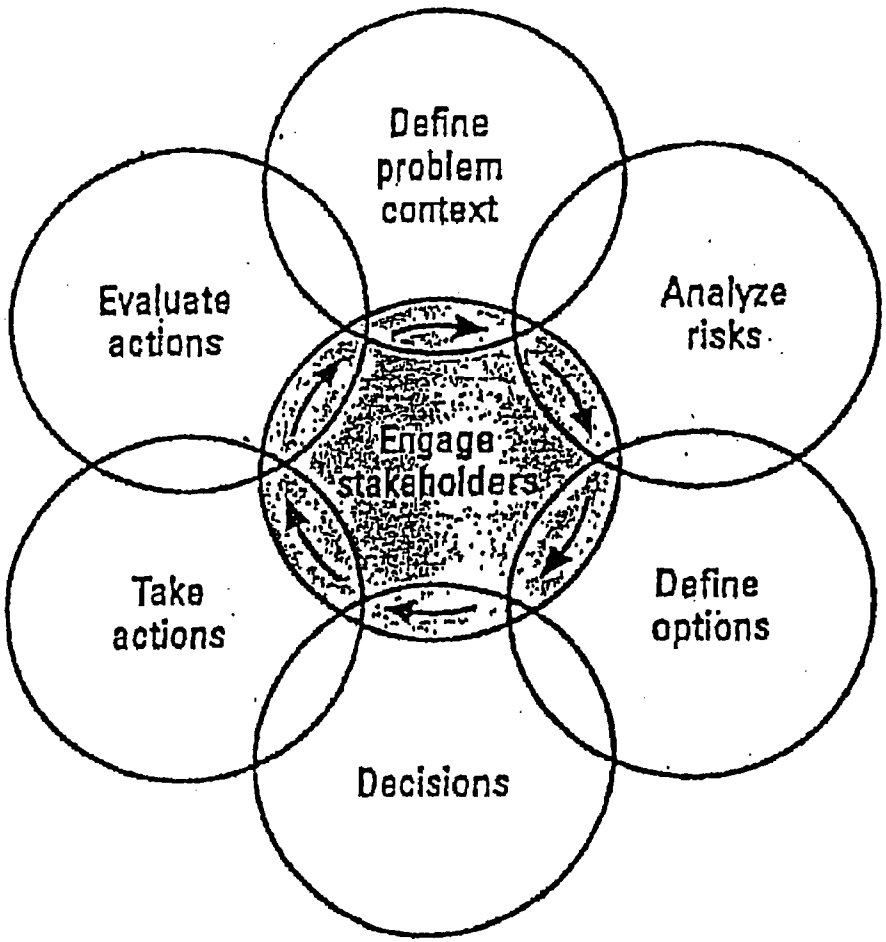
Questions Please call Jeff Morris (202-564-6756) if you have any questions about your presentation, or about other aspects of the workshop series.

Follow-Up Jeff will schedule a conference call with all presenters about a week before the workshop, as a final check-in to answer questions and address any remaining issues.

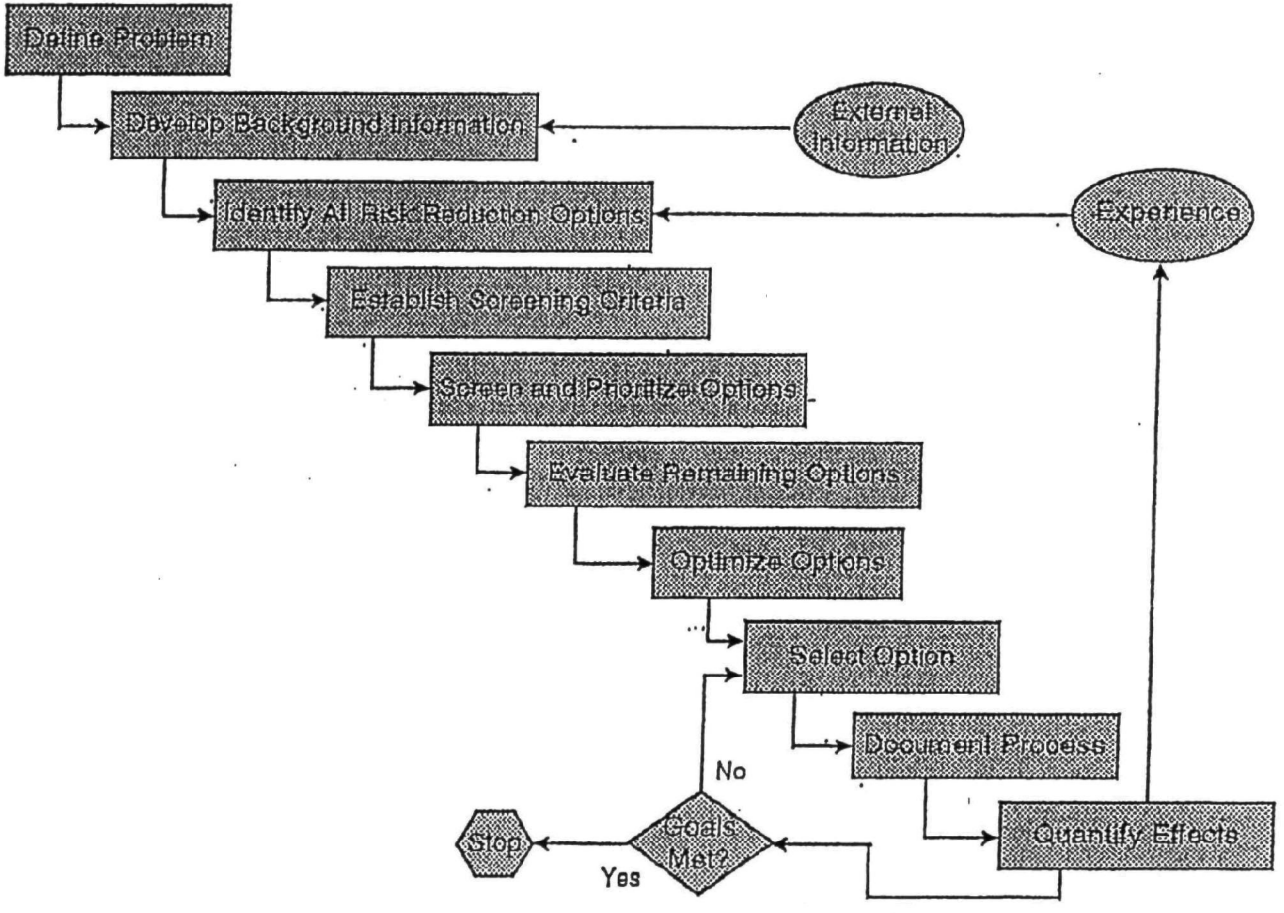
Appendix D
Risk-Management Models



From NRC, 1996 Understanding Risk: Informing Decisions in a Democratic Society

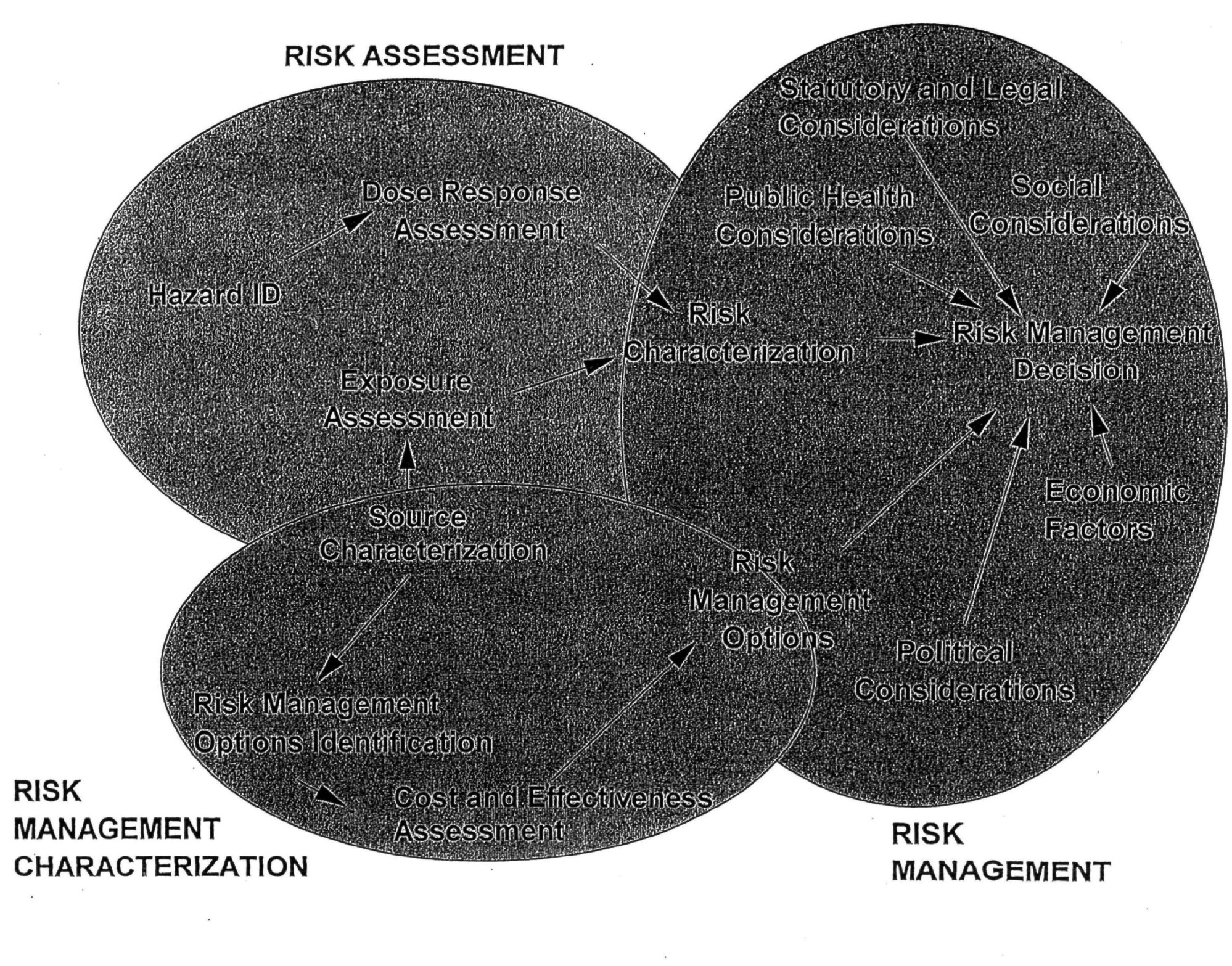


From Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, Framework for Environmental Health Risk Management (Vol.1), and Risk Assessment and Risk Management in Regulatory Decision-Making

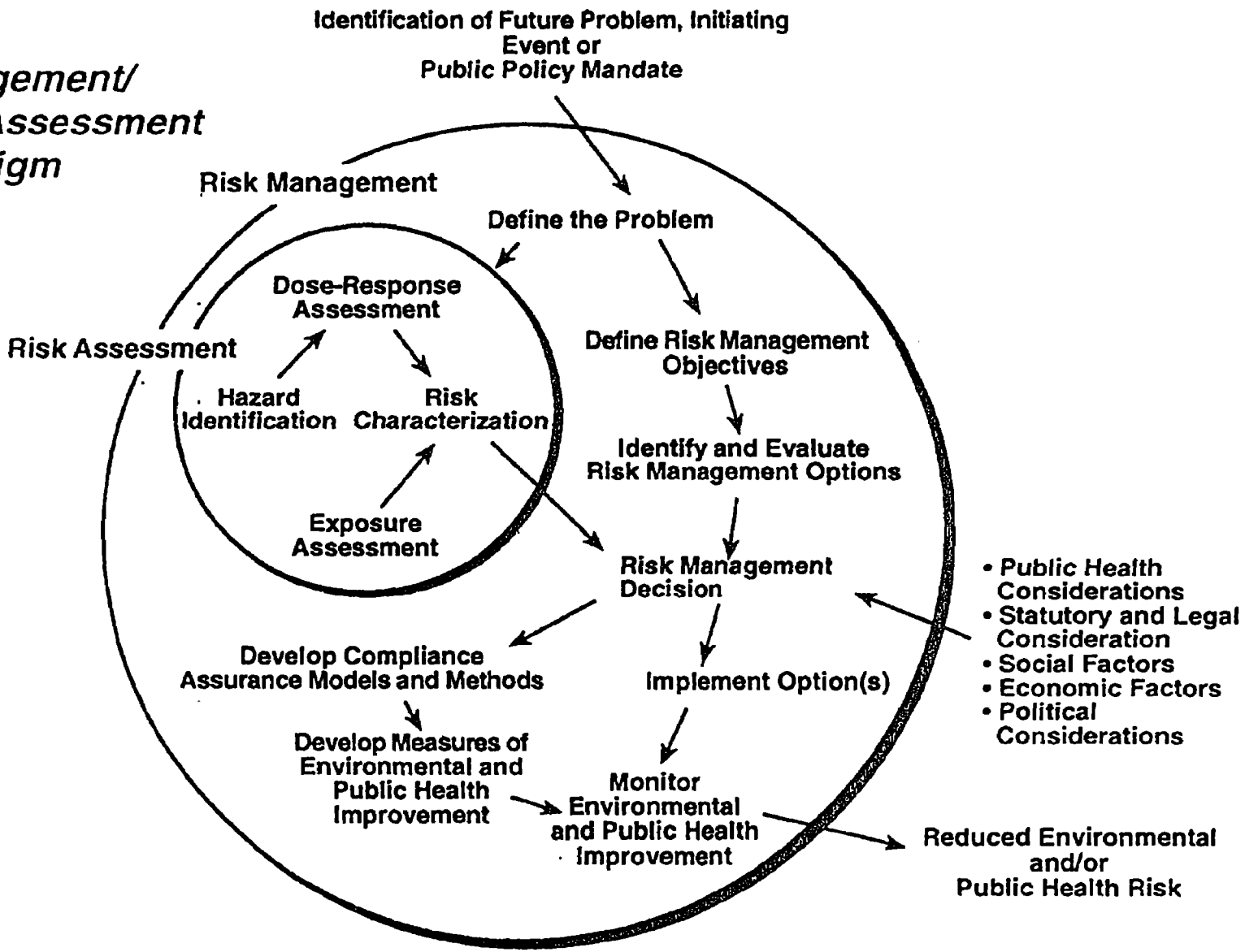


Risk Reduction Option Selection Methodology

From USEPA Science Advisory Board - Integrated Risk Project (Risk Reduction Options Subcommittee)


RISK ASSESSMENT
Dose Response Assessment
Hazard ID
Exposure Assessment
Source Characterization
Risk Characterization
Statutory and Legal Considerations
Public Health Considerations
Social Considerations
Risk Management Decision
Economic Factors
Political Considerations
Risk Management Options
Risk Management Options Identification
Cost and Effectiveness Assessment
RISK MANAGEMENT CHARACTERIZATION
RISK MANAGEMENT

Risk Management/ Risk Assessment Paradigm



Risk Management/Risk Assessment Paradigm

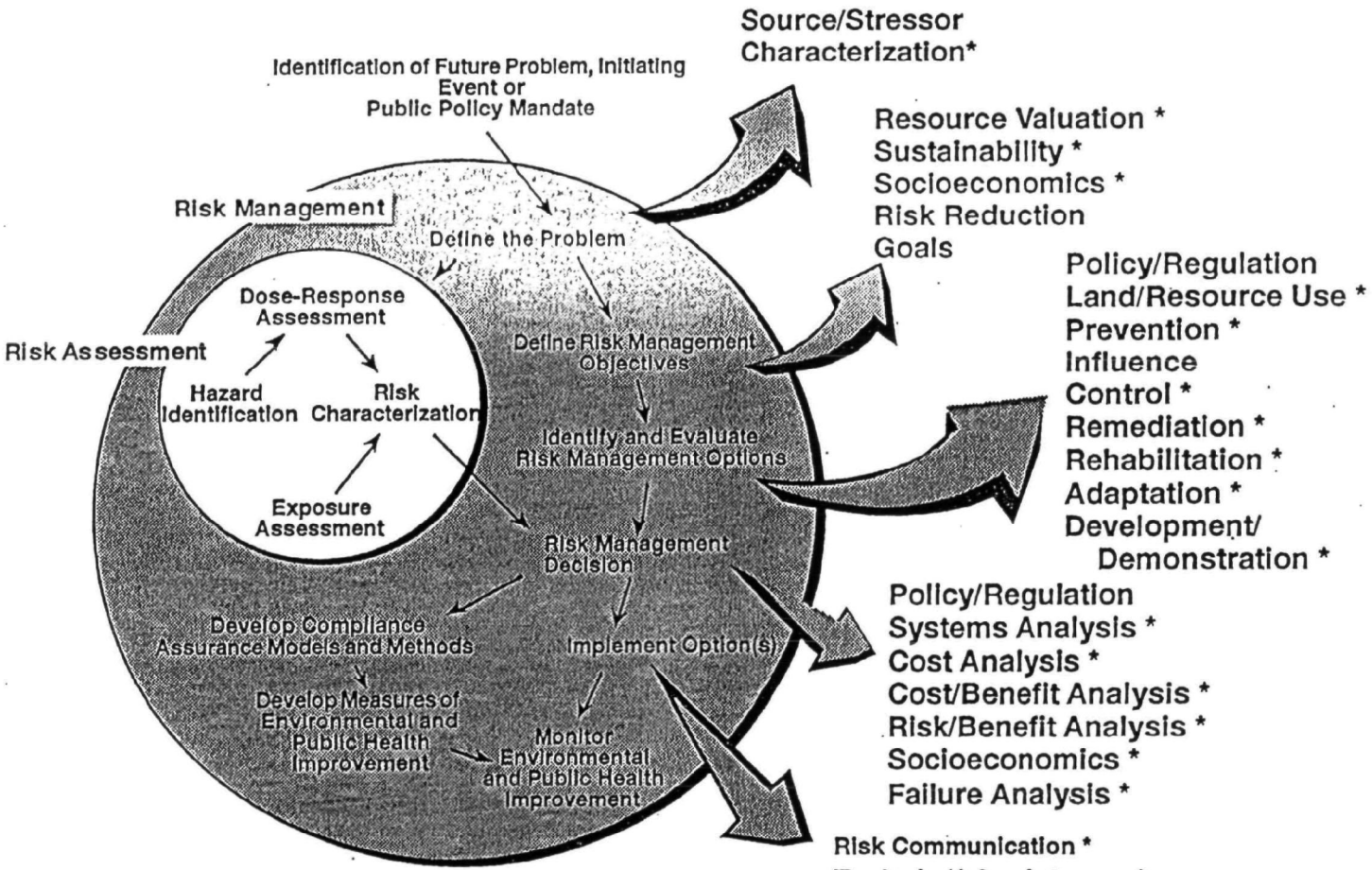


TABLE 1

Comparison of commonalities and differences among frameworks

In spite of differing objectives, ages, nations of origin, and sponsoring agencies, a number of critical themes are common to all frameworks. Tabular entries provide summary descriptions of the stated development purpose and key conceptual innovation of each framework. Agreements among frameworks suggest likely future changes in risk assessment and risk management processes. Differences reveal temporal changes in attitude toward the measurement and management of risk.

Issue	U.S. Risk Commission 1997	Canadian Standards Association 1996	National Research Council 1996	U.K. Department of the Environment 1995	Australia/ New Zealand 1995	U.S. EPA 1992	The Netherlands 1989
Framework's prime objective	Risk management	Environmental decision making	Risk characterization	Risk management	Risk management decision making	Risk analysis	Risk reduction
Assessment versus management	Explicitly management-oriented	Assessment embedded in management	Explicitly management-oriented	Assessment embedded in management	Explicitly management-oriented	Explicitly assessment-oriented	Implicitly management-oriented
Decision making	Decision-oriented, comments on principles and techniques	Decision-oriented, identifies specific decision points	Decision-oriented, decision making used for problem solving	Implicitly decision-oriented, requires balance in decision making	Decision-oriented, stresses a priori criteria for decision making	Not decision-oriented, decisions deferred to risk management	Decision-oriented, includes specific regulatory objectives
Stakeholder input	Strong emphasis on input use	Weak emphasis on input use	Strong emphasis on input use	Implicit emphasis on input use	Strong emphasis on input use	Implicit emphasis on input use	Implicit emphasis on input use
Role of science	Necessary for risk management decision making	Necessary for risk estimation	Necessary for assessment, but insufficient alone	Necessary for risk management decision making	Necessary for risk estimation	Necessary for risk estimation	Necessary for risk estimation
Socioeconomic valuation	Viewed as useful in decision making	Excluded in decision making	Used to broaden risk understanding	Used in decision making due to resource limits	Notes need for cost–benefit analysis	Not included	Costs used to select among regulatory options
Uncertainty analysis	Prefers qualitative to quantitative methods	Requires quantitative methods	Prefers both qualitative and quantitative methods	Stresses qualitative and quantitative methods	Requires qualitative and quantitative methods	Requires quantitative methods	Requires quantitative methods
Risk characterization	Should be both qualitative and quantitative	Emphasizes quantitative approaches	Should be both qualitative and quantitative	Will be partially qualitative due to information gaps	Can be either qualitative and/or quantitative	Emphasizes quantitative approaches	Emphasizes quantitative approaches
Risk prioritization	Important in risk management	Uses qualitative *de minimus* and *de maximus* ranking	Implicit in risk management	Necessary but not always precise	Core management activity completed using criteria	A derivative property of repeated assessment	Completed by comparing risks to standards
Linear versus iterative	Iterative at all stages	Iterative between assessment and management	Iterative at all stages	Iterative at all stages	Iterative at all stages	Iterative between assessment and management	Linear with implicit feedbacks
Key innovation	Includes social, ethical, and economic values in risk analysis	Recognizes the primacy of management over assessment	Recognizes the analytic–deliberative nature of risk-based decision making	Explicit use of the precautionary principle in the face of uncertainty	Emphasizes the comparison of risk to a priori decision criteria	Formalizes the problem identification phase	Specifically states numerical management standards

Appendix E
Breakout Group Flip Chart Transcriptions

Breakout Group 1 AM

Key Points:

Think of as principles - not too much detail (such as guidance, not checklists) not too directive - examples /cases
All models could work - there is variability however.
Decision made without a process - need to recognize.
Problem definition is different for different cases - different users - issues (geographic, chemical, technical, watersheds, regions, states)
Model/s put forward need to be sensitive to definitions - get everyone on the same page.
Driver/s for starting the process (legislative, public, data)
Components in the right egg need expansion and then integration into those eggs.
In many instances programs are doing the left-bottom egg but bringing it together would be useful
Like the idea of a circular diagram with an exit point.
A light framework (too detailed, too general - need a middle ground)
Do RA - Determining acceptable risks using RFCs (range) (decision process)
How much data do you need to support a concern and action about a risk?
What is the trigger/criteria for doing something (recognize that there is a trigger - different implications for different programs)
Decision-makers will be different (local/state) individuals
Coming out of single chemical single site to a more multi-media, multi-issue problem
Go to situations that are not mandated (RAs) to doing RAs because it is a good thing
How do we handle the issue of eco-risks
Iterative (parallel nature of RA/RM) overpowering impacts
Stakeholder leverage $$ implications
Integrating all components is complex
Awareness of larger community / stakeholders
We think we know best how to do it - engagement means change in direction
Gathering data for evaluation
Insurance industry risk reduction

Breakout Group 1 PM

RA is well defined: RM is not as well understood.
Exception is dealing with cumulative risk
All models can work in light of what we heard Day One.

- Superfund guidance does not look that different
- Right side of 3-egg diagram is not neat and clear – we do bottom left at OAQPS.

Process looks like a lot of processes – need to move toward the concrete.
Uncertainty is a predicament – all models seem to need a high amount of data.
We make many decisions without all of the complexity (gut-intuitive - SAB)
Need a way to screen
Models set up to deal with traditional problems.
Many of the models are data driven
We know the guts of what we wanted to do – become too prescriptive, characterize, etc.
Variety of process can be used
Framework with a light touch – suggestions – process police
Some want concrete – some want bigger picture
Too restrictive – no flex
Need a way to make suggestions with some detail
Give examples and guidance helpful insights
Think of as principles
Circular diagram speaks – iterative approach, tiered approach
Stairway diagram says we can stop – go- take and evaluate
Important to consider case-by-case
Make mention of defining the problem
Define problem – what does that mean? Have a broad definition / policy.
Scoping exercise to understand the problem
Drivers: Public input, monitored data, mandated directive.
What is the scale – chemical, geography. Regions can then invest $ in largest environmental problems
There are a bunch of clients
Problem ranking – how important is it – need to set priorities
Need to blow-up the components in the right egg
Appealing to do the left side even though most or all offices do.

SUMMARY

Preliminary Issue: Risk Assessment
Determining acceptable risks (1x10-6?)
Generating sufficient data
Risk actions are triggered by different groups (e.g., PO/RO using different criteria)
Increasing variety of risk management decision-makers
Moving from single issues (chemicals) and sites to multi-media, multiple issue problems
Non-mandated RA / RM options.
Human Health vs. Eco-risks
Iterative parallel nature for RA/RM options –overpowering impacts
Stakeholder leverage/$$ implications
RM paradigm – complex system with multiple component analysis

Larger group of stakeholders - non-traditional groups such as insurance and banking
EPA knows best no longer acceptable

Breakout Group 2 AM

Up-front communication between RM and RAs.
Identify roles of RM and RA
Could be narrow or broad definition of what a RM is.
Might be situation dependent
Depends on the people involved
There should routine interaction as frequently as needed between the RA and the RM.
Characterizing "the source" is a critical issue.
policy
diversion of resources
opportunity cost

Consider:

Incorporation public input
situational - review of draft, public meetings
resource dependent
how to get fairly involved
Should also be required in risk-management decisions:
clarity
consistency
transparency
reasonableness

Consider the various other inputs to the risk-management decision

Documentation issues:
How decision made
How justified
Who is the reader
Consider FOIA
Characterizing uncertainties
What options review and how
Superfund is a good model

SUMMARY

ID Roles and communicate up-front
Risk assessors/managers
Team members
Public
Other with input to process
RA/RM process and policy
Document Decision - Show how we got there including:
Program mandate
options considered
data considered and used
uncertainties
Interactions with interested stakeholders - internal and external

---

Breakout Group 2 PM

Type of risk drives information needs, e.g.:
acute or chronic
immediate or delayed
short or long-term
voluntary or involuntary
buy-in or behavioral changes
scope/extent
Tiering based on type/extent of risk (information needs listed above)
Iterative approach, e.g., Superfund model
removal vs. remedial - 9 criteria
Before beginning RA ID management goals, public concerns (to the extent possible)
Alternatives
Type of decision also drives information needs:

- Programs vs. projects
- Scale
- Scope/nature or outcome
- Immediacy of actions

Who is making the decisions?

- EPA
- Other agency

- Public/ individuals

Communication becomes more important
Verification / validation of decisions – did they achieve goals?
What tools will you use for management action?
EPA
Other agency
Voluntary compliance
Measure of success
- How will you know when you get there?
- Connect outcomes to actions

SUMMARY:

ID management goals and public concerns.
Type of risk drives info. Needs tiering
Who is the decision-maker?
What tools alternatives?
Iterative approach, e.g. SPFD 9
Measures of success validation, goal achieved?

Breakout Group 3 AM

Common Elements
Full Set
  Exemptions for User
Generic
  Checklists for Specifics
Identify Multidisciplines
Sources of Options
  Stakeholder Interactions
  Similarities for Various Uses
Mystery in Risk Management

Risk Assessment not only input to Risk Management
  Economics
  Engineering Limitations
  Politics (will of people)
  Stakeholders
  Implementation
  Transaction Costs
  Legal/Regulations

Defining Options
  Risk-Assessment Contributions
  Attorney
  Chemists
  Economists

Ecologists
Toxicologists
Stakeholders
Social factors (minimal)

Risk Assessment and Risk Management both part of decision
More overlap
Maybe one process

(Exhibit 1 graphic)
Feedback
Risk Assessment → Risk-Management Options → Risk Assessment → Risk-Management Decisions

Mulkey Eggs
- Important Feedback Loops
- Focus on Risk Management

Agency's Prime Reason for being is Risk Management
- Add more input factors

Sequential Process (2)
- Simplicity
- Overview
- Needs structure behind it
- Stakeholder Important in All
- Education
- Input (e.g., social, economic)

Value in Identifying factors for Consideration
Cannot Totally Demystify
Risk Assessment not only input to Risk Management

Breakout Group 3 PM

Case Studies
- Across the board
- Did we see differences in info/processes in models discussed this AM?
- MAIA – strategic thinking vs. RM could ID areas for future RA and decisions
- MAIA – Risk characterization and tools – not necessary RA to take action
- Continue to characterize to verify actions or adjust RM
- Clarify use of surrogates

Did we see the RA/RM iterative process?
- In Ozone and pesticide with integration of regulations

Superfund Case Study was more linear RA _ RM.
Use of case studies and affect on controls in the absences of animal studies.
Source of RM options – role of individual or EPA?
Risk communication as a tool to get support for risk management
Communication with stakeholders as a strategic tool –
- Role of stakeholders and neutral party "jury"

Reinforcements from this morning
- Flexibility

- Iterative process

Where do we go from here?

Clarify factors that should be considered and how to value each.

Open and iterative process with input from stakeholders and communication with those developing risk-management options.

Risk-management option developers communicate with decision-makers.

Transaction costs not often taken into account – part of reality of process

It will be awhile until Agency gets to "the process" for decision-making

- Diverse set of risk managers
- Many different players

What would a risk management decision-making institute deliver if it existed?

"People like color" T. DeMoss, 1999

Breakout Group 4 AM

- All relate RA and RM
- All are useful
- All are linear
- Linearity may not be so useful for presenting information
- Statutory constraints on use of models
- Some are useful for certain cases; fitting models/options to cases is complex; need more support
- Options need to be resource -based
- Models are deficient in defining input into various options (except NRC model)
- NAS model contains information exchange
- Highlight iterative vs. linear process (e.g., a shaded box to note iteration)
- Also highlight continual stakeholder input, but: nature and involvement of stakeholder should vary at particular steps
- Olive-cell chart vs. master-card chart highlights risk assessment as a subset of risk management, but, should include non-RA factors as equally important
  for example: multiple 'mitochondria' for cell rather than a nucleus
- Suggestion: don't use the word "paradigm." How will the (paradigm - for the lack of a better term) be used? To guide research? To educate the public?
- Options identification merits its own subset
- There is doubt that a single model can incorporate all approaches
- *Reaction to above*: The model is helpful to allow users to pick and choose which elements help
- Re: Purpose of the model
  1. A guide to risk managers in program offices
  2. To be used within ORD - to serve as a reminder of factors that may not obviously spring to mind
- A variety of diagrams exist with limited utility; but, should model define research, or, should ORD respond to program offices' needs who use the model

- PURPOSE: Questions:
  1. Is it useful for program and regional offices in conducting their work?
  2. If it is useful, is it useful to ORD in assisting program and regional offices?
  3. Will the model indicate new types of research for ORD?
  4. Will the model be useful for public discourse?
  5. Will the model help influence the way risk management is conducted?

- Answers:
  1. You cannot have #'s 2 and 3 without also having #1
  2. Yes to #1 - Model serves as a checklist
  3. Yes to #1 - For example, the need for stakeholder/community involvement

- Question: Are there elements in the/a model that have been ignored?
- Answer: No, but model can be useful to communicate risk management to regions
- Models are lacking in an evaluation stage (success or performance metrics)
- Question: Which models come close to reality?
- Master-card model is more realistic/nuanced than the Science Advisory Board model
- Answer: Olive-cell model is closer, but add feed-back/evaluation loop
- Need to formalize risk-management thinking
- The olive-cell model is OK but there is a need to simplify at a broad level
- The master-card model is good because it highlights the interplay of science/economic/political concerns
- A suggestion: remove arrows and put things in organelles
- *Reaction to above*: The arrows show flow
- The Presidential Commission model has all of the necessary elements; it just needs to add iteration
- Question: What is the utility of the models to the program?
- Answer: Economic/political is the most important - the master-card model is most useful
- Answer: As explicit checklist
- Then, just have a checklist
- The model should be flexible to accommodate different environmental issues

---

Breakout Group 4 PM

- Case Studies
  - Document examples of successful and unsuccessful approaches/actions, order/categorize examples
  - Provide a historical perspective
  - Use actual cases to create the model
  - Provide a feel for te diversity of issues
- Suggestion: Use a contractor to:
  - Pick relevant issues
  - communicate with program offices
- Decision-making is a matter of managing constraints
- There is difficulty in incorporating risk assessment into risk management during decision-making
- Uncertainty in risk assessment must be dealt with (uncertainty/safety factors)
- Program and regional offices can object to ORD involvement - trust issue
- ORD may disagree with program or regional office
- Inter- vs. intra-agency involvement
- Programs want to keep decision-making within the program, ORD provides technical support
- Traditional support is still needed, but now there are more issues to deal with:
  - Do program offices need further information or support from ORD/technical staff? (stakeholder involvement, etc.)
- Items on the "checklist" or model(s) that program offices need input on, or that are missing altogether? That ORD can provide?
  - Guidance on a process/options - be part of the thinking process in areas that ORD has knowledge

- Especially if ORD participates early in the process
- Focus on prevention options as a solution to a problem - not reflected in the models

- Think more broadly about what risk management means: Views:
  Approach processes thinking preventively up front
  vs.
  Establishing risk before approaching risk management
- Industry is focused on profits vs. preventing problems:
  - Low-cost drives decisions
  - Regulation drives more responsible actions
- Risk assessment is a reductionist approach (what we saw this afternoon)
  - Cost-effectiveness
  - Communication
- **Research on the 'bargaining' process is needed** (in red ink)
- 'Outliers' can play a big part - how do you deal with that (Extremists)
- Market-based approaches (Emissions trading)
- Other strategies for risk management; when are the different strategies appropriate (advantages and disadvantages of each strategy)
- Uncertainty surrounding decisions - communication of that

SUMMARY

- What are some next steps that ORD could take to understand and flesh out the risk-management process?
  - More case studies of risk-management decisions
  - Working more closely with the program and regional offices in decision-making process (e.g., reg. support)
- Where should ORD scientists in general be involved in the risk-management process?
- P2 (prevention) is not adequately represented in the frameworks:
  - The frameworks work well for large, well-recognized problems
  - They do not allow for looking at P2 (prevention) options as new management processes are being developed; Industry should handle?? ORD?
- What are some key (newer) areas where ORD could contribute through research to the present risk-management processes:
  - Cost and effectiveness issues
  - Evaluation of program's overall effectiveness
  - Negotiation process
  - Communicating risk-management options, etc.
  - Market-based systems

Appendix F. Hand-Outs

Information Needs for Risk Management Decision Making

The Superfund Perspective

David Cooper, Senior Manager for Risk
Office of Emergency and Remedial Response

June 15, 1999

MAJOR SUPERFUND THEMES

- **Protect Public Health and the Environment**
  Identify sites where releases of hazardous substances occurred or might occur and pose a threat to human health and the environment

- **Every Site is Unique**
  An analysis needs to be done for each site to determine the appropriate action

- **Responsible Parties Pay for Cleanup Actions**

  Introduces liability issues

Superfund: A Complex Environmental Program

- Addresses emergency removals and long-term remedial action
- Complex Network of Laws, Regulations, Guidance
- Requires Coordination with Governments, Public, Responsible Parties
- Addresses Multiple Chemicals, Media, and Pathways
- Resource Intensive
- Multi-disciplinary

Remedial Investigation/Feasibility Study

- **Nature and extent of contamination**
- **Health and environmental risks**
- **Range of cleanup alternatives**
- **Analysis of alternatives**

Standards for Superfund Risk Management Decisions: The Nine Criteria

Threshold Criteria

1. Overall protection of human health and the environment
2. Compliance with Applicable or Relevant and Appropriate Requirements (ARARs)

Primary Balancing Criteria

3. Long-term effectiveness
4. Reduction of toxicity, mobility, and volume
5. Short-term effectiveness
6. Implementability
7. Cost

Modifying Criteria

8. State acceptance
9. Community acceptance

Rules of Thumb for Superfund Remedy Selection

❖Program Goals

The remedy will:

- *protect human health and the environment*
- *maintain protection over time*
- *minimize untreated waste*

❖Program Expectations

Appropriate remedial alternatives will:

- *use treatment to address principle threats, wherever practicable*
- *use engineering controls for low long-term threat*
- *use combination of methods to protect human health and the environment*
- *use institutional controls to supplement engineering controls to prevent or limit exposures*
- *use innovative technology (if better,cost efficient, less adverse risks)*
- *return usable groundwaters to beneficial uses*

CERCLA (Section 121) Remedy Selection Requirements

1. Protect human health and the environment
2. Comply with federal and state ARARs
3. Use permanent solutions and alternative treatment technologies to the *maximum extent practicable*
4. Cost effective
5. Satisfy a preference for treatment, or explain why not
6. Include State and community participation

Sources of Uncertainty in Risk Management

- Confidence in the Data
- Level of health protection, risk reduction
- Degree of stakeholder acceptance
- Economic impacts,
- Implementation, efficacy of remedy

Other Valuable Information

Efficacy and Limitations of Alternative Remedies

- Natural attenuation
- Fate and transport of persistent contaminants

Future Land Uses

- Realistic, reliable predictions
- Enforceability and longevity of institutional controls

Children's Health

- Early life exposures
- Toxic effects

Accuracy of Risk Assessments

- Are the methods "overprotective" or unrealistic?
- Are some important risk factors overlooked?

Conclusion

Superfund risk management decisions are grounded in-

- CERCLA's *principle requirements*
- The *nine criteria* for evaluating remedial alternatives
- Superfund Program's *goals and expectations* (40CFR300.430(a)(1)(i,iii))

Superfund decisions could benefit from-

- Reliable future land use information
- More data on cost-effective technologies for reducing risk
- Cross-agency discussions

Identify, Generate, Analyze, Transfer Information

Case Study for Stratospheric Ozone

For Use Only Within EPA

William J. Rhodes

U.S. Environmental Protection Agency
Air Pollution Prevention and Control Division
National Risk Management Research Laboratory

June 16, 1999

(information contributions from Richard Zepp, NERL and Jennifer Ormezavaleta, NHEERL)

- **Announcement**
  1974 Rowland and Molina

- **Science: 1974 to early 1980s**
  stratospheric impact and assessment
  biological and climatic effects research
  including UV
  NAS conclusion

- **Industry**
  Outcry: innocent until proven guilty
  Identify rights of people with rights of chemicals

- **Public & Risk Management**
  - **CFCs in aerosols**
  - **1978 ban CFCs as propellant**
  - **Exemptions: no alternative & product is essential**
  - **Canada, Sweden, and Norway join U.S.**
  - **Problem solved?**

- **Dialog**
  - **NAS and industry took opposite sides**
  - **1980- Alliance for Responsible CFC Policy**
  - **EPA issues notice to regulate**
  - **Industry objects**
  - **Executive Office rules out regulations**

- **Science**
  - **CFCs increase for other reasons**
  - **1982 Rowland et al. announcement**
  - **1984 British Antarctic Survey**
    - **EPA Administrator denounces as scare tactic**
  - **1985 Vienna Convention**
  - **1985 EPA sued by NRDC**
  - **1985 New evaluation of CFCs**
  - **Is there a problem?**

- **EPA**
  - **New Administrator, Lee Thomas:**
  - **may need to act in near term to "avoid letting today's risk become tomorrow's crisis"**

- **Risk Management (RM)**
  - **If a problem, what do we do?**
  - **OAP- Rand Corp for technology support**
  - **Source Characterization**
    - **chemicals and sources**
    - **detailed reports**
  - **"Control" Options**
    - **potential evaluated across industry**
    - **control per chemical**
    - **end of pipe versus alternative technology/prevention**
    - **estimates of cost and benefits**
  - **1986 Regulatory Impact Analysis**
  - **International concerns and negotiations**

- **Science**
  - **Simultaneously study potential effects**
  - **SAB raises importance**
  - **Remember 1982 Rowland et al.**

- **Industry**
  - **"Theorized depletion" could not be happening**
  - **Economy of Nation and worker safety**

- **Early EPA conclusion (not unanimous)**
  - **Need to start "controls" before science is complete**
    - **consequences of inaction**
  - **OAP evaluates RM options**
    - **difficulty of controlling widespread and variety of sources**

- **RM**
  - **Traditional approach**
  - **Most ODS uses, traditional seemed impractical**
  - **Consider:**
    - **replacement chemicals**
    - **alternative technologies**

- **Conclusion**
  - **Start small:**
    - **reductions in CFCs**
    - **flexibility for science and risk management**
  - **Confluence:**
    - **ozone hole**
    - **threat of UVb increases**
    - **promise of limited solutions**
  - **1987 Montreal Protocol**

TO THIS POINT,

ALL ACTIONS LEAD TO

FIRST AGREEMENT

BEYOND LIMITED

AEROSOLS 1978

- **Approach for RM**
  - **Workshop (1987, OAP lead)**
    - **multi-nation, multi-organizational**
    - **privately industry had one chemical**
    - **industry saw no further need for research**
    - **industry/academia: Federal Gov't/EPA should**
      - **fund development of long-term solutions**
      - **in case science indicates the need**

- **Simultaneous Actions**
  - **Some industry proactive**
    - **electronics/cleaning/solvents industry**
      - **saw opportunity**
  - **Key in cleaning: Mil Specs**
  - **Large chemical companies stop research**
  - **Halons and methyl bromide**

- **Chemical Industry Position**
  - **No solutions available**
  - **No controls are feasible**
  - **Wait and see**

- **Approach for RM**
  - **ORD and OAP agreement on electronics cleaning**
  - **ORD and OAP agree on new chemicals**
    - **insurance policy**
    - **stimulate industry**
    - **show potential**
    - **counter industry claims**

- **ORD Chemical Data**
  - **Competitive cooperative agreements**
    - **synthesized and determined properties of new chemical classes**
  - **Data: chemical, physical, and thermodynamic properties**
  - **ORD defines and evaluates data**
    - **some potential**
    - **refrigeration uses, halons**

- **Simultaneous Actions**
  - **ORD shows possibility**
  - **Science shows problem looks serious**
    - **minimal data**

- **Approach for RM**
  - **1988 Foam industries**
  - **1989 Aerosol replacements identified**
    - **28 categories detail on non-CFC formulations: HCs, DME**
    - **alternative dispensing devices availability, effectiveness, descriptions, formulations, uses**
    - **7 categories reformulate to reduce**
  - **1989 Destruction of CFCs/halons**
  - **1989 ORD/OAP work with MACS**
    - **unbiased evaluation of recycling technology**
    - **S&A protocols, impurities, age/condition of system**
    - **compare to specs; effectiveness of cleanup systems**
    - **establish agreement on voluntary criteria**

AT THIS POINT,

ORD DEMONSTRATED

THE NEED FOR AND THE

AVAILABILITY OF

SOLUTIONS

- **RM Approach**
  - **1990 Clean Air Act Amendments**
    - **SNAP Policy established**
      - **technical support to evaluate any alternatives**
      - **continues today, but diminishing expertise**

- **Simultaneous Actions**
  - **1990 London agreement**
  - **ORD larger quantities of new chemicals**
    - **results promising**
    - **expand data**
  - **Chemical industry reinitiates R&D**
  - **1991 using ORD results, new chemicals pursued**
    - **alternative technologies are commercialized**
    - **solutions outpace science and regulations**
    - **economic advantages: better, safer, more reliable**
    - **$ profits available**

- **Science**
  - **UV and cataracts from Effects Lab**
  - **Early 1990s Brewer UV**
    - **shows changes due to ozone not aerosols**
    - **sunburn and DNA effects identified**
  - **Enhanced UVb estimated**
  - **Eruptions of volcanoes**
  - **Health**
  - **Terrestrial**
  - **Marine phytoplankton 92-94**
  - **Importance of dissolved organic matter**
  - **Troposphere**
  - **Interactions of most of above**

- **RM**
  - **1991 Aerosols manual to convert from CFCs**
    - **supply, product reformulation, equipment conversion, safety**

- **FINAL ACTION**
  1992 Copenhagen
  Industry continues to offer some ODS substitutes

- **MOST ACTIVITY AFTER THIS WAS AND IS TO UNDERSTAND EFFECTS, TO LESSEN IMPACT THROUGH PREVENTION/ADAPTATION, AND TO CONTINUE MORE RAPID MITIGATION**

- **Risk Management**
  - **Some replacements high GWP**
  - **Benefits of near-term ozone outweighed long-term Global Change**
  - **Need to find replacements for Global Change**
  - **Industry not concerned about Global Climate Change**
  - **1993 Surplus CFCs/halons**
    - **estimate bank**
    - **transformation process**
    - **market for reformed chemicals**
    - **evaluation of transformation technologies**
  - **Utilize ORD expertise on Navy CFC-114**
    - **computer modeling of cooling systems and alternative chemicals**

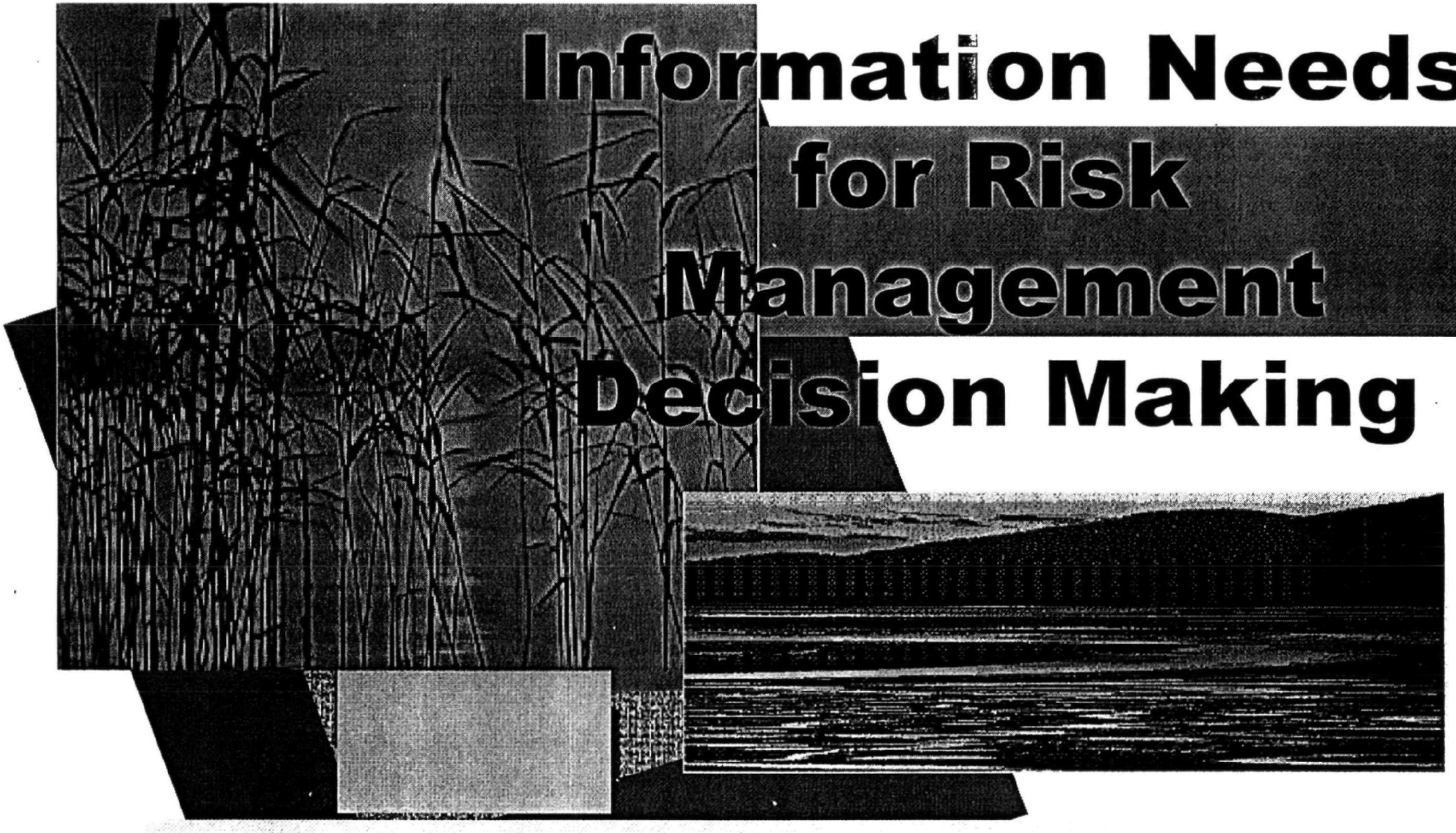
- **Science**
  - **UV on crops 94-97**
  - **Impacts of UVb on coral 94 and continuing**
  - **UV and risk of infectious disease (workshop) 95**

- **Risk Management**
  - **Navy selects ORD new chemical**
    - **savings of over $300 million and large source of CFCs**
  - **Avoidance of DoD resistance was a prime factor**

- **Science**
  - **UVb on amphibians 95**
  - **UV effects on immune system 97**

- **Risk Management**
  - **HFC concerns**
    - **tested MACs for**
      - **HFC-134a impurity problems 94**
      - **new chemicals 96/97**
      - **human exposure to refrigerants 98/99**
    - **fastest growing GHGs**
    - **alternative technology in refrigeration**
    - **Program Office support in future**

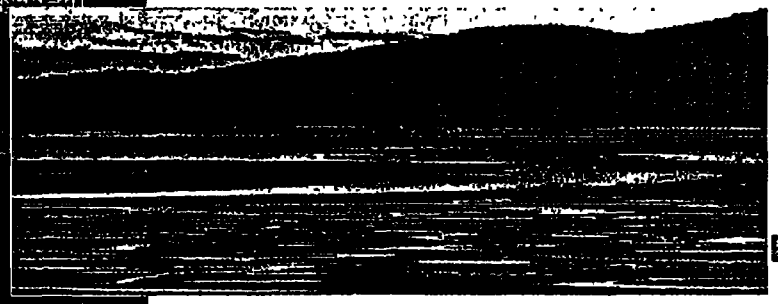
- **Lessons Learned**
  - **Science and Risk Management freedom**
  - **Politics works best after facts are known**
  - **Industry usually has short-term financial interests**
  - **Industry needs to be at the table**
  - **ORD and Program Office really need to work together**
  - **ORD needs to understand Program Office needs**
  - **Program Office needs to let ORD have some freedom**
  - **Will only happen with familiarity building trust**



Information Needs for Risk Management Decision Making

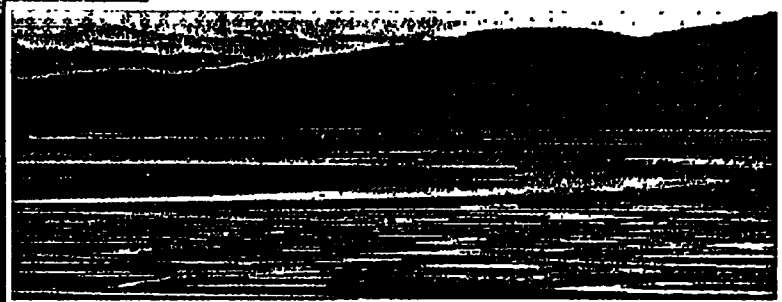
John Meagher

"A Wetlands Manager's Needs"



Clean Water Act Objective (Sec. 101(a))

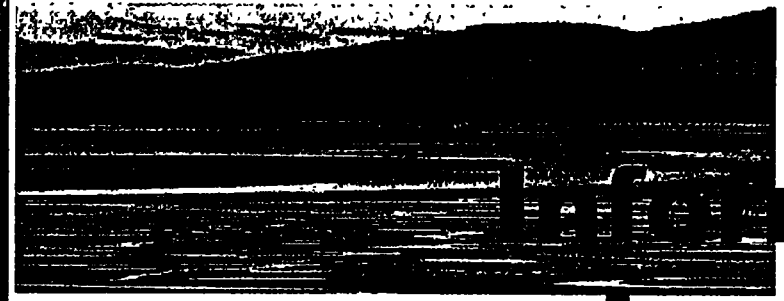
"...to restore and maintain the chemical, physical, and biological integrity of the Nation's waters"



Watershed Management

BASIC PREMISE

Involve all stakeholders in integrating environmental resources and diverse land uses in a manner that balances ecological, social, and economic needs.



Information Needs for Impact Evaluation

- What roles do the individual and collective wetlands play in the watershed?
- What are the overall ecological, social, and economic goals of stakeholders?

  A) Identify the alternative sites/strategies or corrective actions that can reduce environmental impacts.

  B) Are the alternatives economically and logistically feasible?

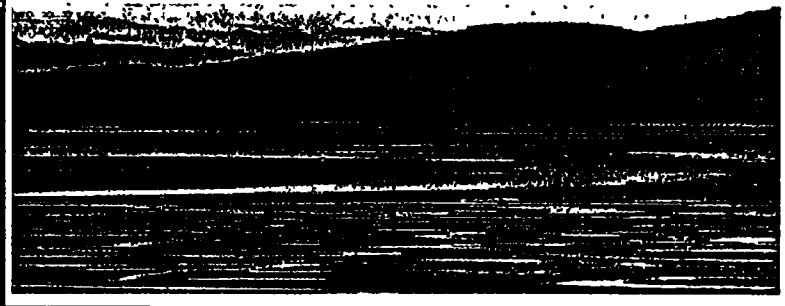
formation Needs

Management tools available to avoid/reduce/offset impacts:

- Clean Water Act
- Local Ordinances
- Financial Incentives

Information Needs for Risk Management

- Methods for predicting landscape development (alternative futures)
- Methods for determining appropriate setback distances
- Methods for implementing Best Management Practices
- Methods for determining width and kinds of buffer strips
- Methods for restoring wetlands

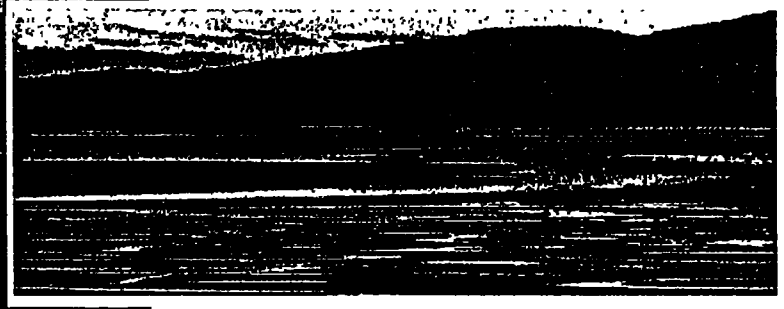


Clean Water Act

SECTION 404

BASIC PREMISE

No discharge of dredged or fill material can be permitted if a practicable alternative exists that is less damaging to the aquatic environment or if the Nation's waters would be significantly degraded



Clean Water Act

SECTION 401

BASIC PREMISE

Provides mechanism to protect water quality, including wetland quality/condition, through aquatic life criteria and beneficial uses.

CWA Section 404

1. Alternatives Analysis

1) Avoids impacts

2) Minimize impacts

3) Compensate for unavoidable impacts

CWA Section 404 cont'd

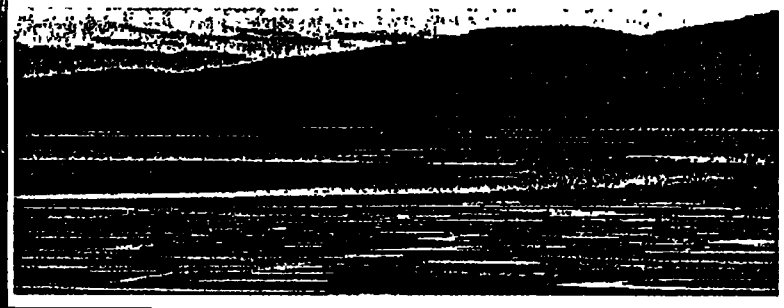
2. Information Needs for Evaluation

- Methods for evaluating and minimizing the consequences of losing this wetland
- Methods for developing alternatives to proposed impacts
- Methods for reducing effects on wildlife and water quality, including migratory corridors and habitats
- Methods for reducing risks from flooding
- Other considerations: environmental justice, economic feasibility, historic/tribal sites, local zoning

WRDA Section 404

Information needs to determine compensatory mitigation:

- Where to locate restoration in the watershed
- What types of restoration are priorities
- What performance criteria are appropriate for the restoration site
- Management strategy to determine environmental benefits of in-kind, on-site vs. off-site, out-of-kind restoration



GPRA Goal

1) Annual net gain of 100,000 acres per year by 20005

2) Enhanced role of restoration beyond compensatory mitigation

VALLEY WOOD PRESERVING Turlock, California

OPERATIONS & ENVIRONS

- Pressure treated wood using chromated copper arsenate.
- Operated from 1973 to 1979.
- Partially paved; overlies sandy soil and shallow aquifer.
- Neighbors include residences, duck farm, and vineyard with domestic wells.

ENFORCEMENT HISTORY

- Operated ~5 years without permit from local water quality authority.
- Neighbors complained in 1979. Chromium in soil (3100 mg/kg) and ponded water (67 mg/L) on site.
- August 1979: Water authority ordered cleanup.
- November 1979: chromium detected in monitoring well on site at 8 ppm (MCL=0.05). County revoked use permit.

SUPERFUND STATUS

- Site added to National Priorities List (NPL) March 1989.
- Record of Decision signed September 1991.

Medium	Contaminant	Risk	Max. Conc.	Cleanup
Soil, surface	Cr(VI)	Current use in risk range; future 10^{-4} to 10^{-2}	30 mg/kg	4 mg/kg
	As		140 mg/kg	2 mg/kg
Soil, subsurface	Cr(VI)		68 mg/kg	5 µg/L
	As		232 mg/kg	5 µg/L
Ground water	Cr(VI)	Current HI=8; future HI=10; 10^{-3}	28 mg/L	0.05 mg/L
	As		2.35 mg/L	0.016 mg/L

SUPERFUND DECISION-MAKING PROCESS

Threshold criteria

1. Overall protection of human health and environment
2. Applicable or relevant and appropriate requirements

Primary balancing criteria

3. Long-term effectiveness
4. Reduction of toxicity, mobility, or volume
5. Short-term effectiveness
6. Implementability
7. Cost

Modifying criteria

8. State acceptance
9. Community acceptance

RM DECISION-MAKING ISSUES: TECHNICAL

Soil cleanup standards

- Leaching standards assume 100x attenuation
- Two leach tests: CalWET and TCLP
- Arsenic
  - level for direct contact vs background

Groundwater

- Treatment with non-degradation policy
- Innovative treatment technology

SITE-SPECIFIC LEACH FACTOR

Time	LF, As	LF, Cr(VI)
1984-85	83	4.7
1988-89	830	8.6
1991-93	10000	11

RM DECISION-MAKING ISSUES: LEGAL

- **Prior to NPL listing, responsible party delayed most response actions.**
- **PRP claimed financial straits.**
- **Costs and cost-recovery (PRP-lead).**
- **Administrative order on consent vs. unilateral order.**

RM DECISION-MAKING ISSUES: REGULATORY/ADMIN

- Three active regulators--U.S. EPA, California DTSC, Central Valley Regional Water Quality Control Board.
- NPL requires compliance with ARARs or waiver.
- Modifying criteria are state and public acceptance.

EPA WORKSHOP

INFORMATION NEEDS FOR RISK MANAGEMENT DECISION MAKING

A REGIONAL OFFICE PERSPECTIVE

Stanley L. Laskowski
Environmental Services
Division Director, Region III

SOME CURRENT ISSUES IN REGION III

(1) **URBAN SPRAWL**

(2) **MOUNTAIN TOP REMOVAL/VALLEY FILLS**

(3) **TRANSPORTATION - NEPA/TEA 21**

(4) **WETLANDS**

(5) **WATERSHEDS/COASTAL**

ENVIRONMENTAL PROBLEMS HAVE MANY RISK MANAGEMENT DECISION MAKERS

EXAMPLES

(1) SPRAWL/TRANSPORTATION

- LOCAL/COUNTY PLANNERS - MPOs, ETC.
- DOT/FHWA
- STATE DOT/STATE ENVIRONMENTAL OFFICES
- NGOs
- EPA

(2) MOUNTAIN TOP REMOVAL/VALLEY FILLS

- OSM
- STATES - ENVIRONMENTAL; ECONOMICS/COMMERCE; DNR
- FWLS
- COE
- PUBLIC
- INDUSTRY
- NGOs

SOME GENERIC NEEDS FOR RISK MANAGEMENT

DECISION MAKERS

(1) LANDSCAPE - ENVIRONMENT CORRELATIONS

(2) CUMULATIVE EFFECTS ASSESSMENT

(3) MULTIPLE STRESSORS ON AQUATIC RESOURCES

(4) REAL TIME INDICATORS

(5) SOCIAL/ECONOMIC/ENVIRONMENTAL JUSTICE

LANDSCAPE - ENVIRONMENT CORRELATIONS

(SPRAWL; MTR/VF; TEA 21)

(A) CORRELATE

- **LANDSCAPE (e.g., FOREST COVER; IMPERVIOUS AREAS; SLOPE)**

AND

- **ENVIRONMENTAL INDICATORS (e.g., WATER QUALITY; SONGBIRDS; AQUATIC LIFE)**

(B) DEVELOP BREAKPOINTS/THRESHOLDS

CUMULATIVE EFFECTS ASSESSMENT

(SPRAWL; MTR/VF; TEA-21; NEPA)

- **HOW TO DEFINE GEOGRAPHIC BOUNDARIES**

- **HOW TO EVALUATE OVER TIME**

- **WHAT IS CAPACITY TO WITHSTAND IMPACT (RESILIENCY)**

MULTIPLE STRESSORS ON AQUATIC RESOURCES

(WATERSHED MANAGEMENT; COASTAL/ESTUARIES)

- **HOW MUCH AQUATIC LOSS IS DUE TO VARIOUS STRESSORS - e.g.,**
  - **WETLANDS LOSS**
  - **OVER FISHING**
  - **LANDUSE CHANGES**
- **WHICH STRESSORS COULD BE CONTROLLED**
  - **COST-BENEFIT**
  - **CHANCE OF SUCCESS**

REAL TIME INDICATORS

(BEACHES; WATER SUPPLY)

- **BACTERIAL - OCEANS**

- **DRINKING WATER - CRYPTO SPORIDIUM**

SOCIAL/ECONOMIC/ENVIRONMENTAL JUSTICE

(MTR/VF; TEA 21)

- **ECONOMICS OF COAL MINING**
  - **SITE SPECIFIC**
  - **MACRO - INTERSTATE**
- **ENVIRONMENTAL JUSTICE - DEFINE ENVIRONMENTAL JUSTICE STUDY AREA**

New Directions Workshops — ***Identifying Information Needs for Risk Managers*** **Series**

Workshop II:
Communication and Stakeholder Involvement in the Risk Management Process

Summary Report

Prepared for

Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

September 1, 1999

Table of Contents

Appendices

This report was prepared for the Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, by S. Cohen & Associates, Inc., 1355 Beverly Road, Suite 250, McLean, VA 22101, and Environmental Management Support, Inc., 8601 Georgia Avenue, Suite 500, Silver Spring, MD 20910, under contract number 68-D5-0132, work assignment III-8. For further information, please contact Gerardo Pascual at 202-564-2259.

Preface

The U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) is currently pursuing new approaches for using science to address several topics of importance to the Agency. These topics represent new directions for the EPA in that they transcend the traditional media- or pollutant-based boundaries and encompass a variety of disciplines and specialities. ORD wishes to link EPA staff interested in these topics with the appropriate science staff in ORD to identify areas for collaboration. To accomplish this goal, ORD's Office of Science Policy (OSP) is hosting a series of New Directions workshops between March 1999 and Spring 2000. The workshops will provide a forum to present information and discuss current and future issues on new topics of interest. There are four topic series being presented under the auspices of New Directions: risk management, community assessment, reinvention, and regional science. Each topic series will consist of workshops designed to bring interested staff together to develop a set of action items that will be completed over the course of the series.

The Risk Management workshops are designed to identify the types of information, such as costs and benefits, technological feasibility, community values, and other non-risk assessment information, that EPA managers need and use to inform their risk-management decisions. The first workshop, held June 15-16, 1999 in Washington, D.C., dealt with developing information needs for risk management decision-making. This summary describes the second workshop, held July 14-15, 1999, which discussed communication and stakeholder involvement in risk management. A third workshop may be held, perhaps in conjunction with the third workshop of the Community Assessment Series. The desired outcome of the series is a review and analysis of risk-management processes and information needs for use in the development of a draft unified paradigm for organizing and providing information to risk managers.

The second workshop, *Communication and Stakeholder Involvement in the Risk-Management Process*, had the following objectives: (1) to obtain the perspectives of risk assessors and risk managers on how they communicate during the risk management decision-making process and to discuss how a unified model for providing information could enhance such communication, and (2) to discuss how stakeholder input can add value to the decision-

STATUS OF THIS REPORT

The objective of this workshop (or workshop series) was to bring together EPA scientists from the regions, programs, and ORD labs and centers to discuss issues of common interest. The focus of the meeting (or each meeting) was preliminary discussion among scientists and managers from different parts of the Agency, each with their individual and office-specific information and viewpoints.

As a result, it is important to understand that this report summarizes individual and program-specific perspectives. References to pre-existing Agency information and policies should be credited as such, but none of the individual workshop statements or summaries in this report should be credited or cited as Agency information or policies. Rather, this report is developed exclusively for internal EPA use and distribution as a record of the meeting for participants in each meeting, and for EPA's use in planning future meetings and discussion. EPA staff will use information from this report, as appropriate, to design and conduct workshops or other activities for broader discussion both within EPA and with external participation, again as appropriate.

making process and how such input could be incorporated into a unified risk-management information model.

This report summarizes the information that was presented and exchanged during the workshop. The organization of the report follows the agenda of the workshop. Approximately 35 EPA staff, representing EPA program offices, ORD, and several EPA Regional offices, participated; Appendix A provides a complete list of participants. The two-day workshop was designed to maximize participant input and collaboration; Appendix B is a copy of the final agenda. Appendix C includes copies of the models discussed. Finally, Appendix D gives transcriptions of flip charts and posters produced during the workshop's breakout group discussions.

1.0 Introduction

The New Directions initiative and the Risk Management series were introduced in a presentation by Hugh McKinnon, of the U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD), National Risk Management Research Laboratory (NRMRL). The mission of NRMRL is to enable, assist, and support Agency decision-making. This series is intended to raise the visibility of the risk-management process within the Agency to the same level as risk assessment. By conducting this series of workshops, EPA's Office of Science Policy (OSP), also within ORD, hopes to be a catalyst for discussions and follow-up actions for decision-making. OSP is uniquely qualified for this position since it works with all the program offices within the Agency. OSP seeks to determine information needs and research needs and provides suggestions on how ORD can support the Regional and program offices in the risk-management process. Research needs identified by the workshops in the series will be incorporated into research planning. This work is particularly important at this time, as the Government Performance Review Act (GPRA) spurs the Agency to pay particular attention to the outcome and effectiveness of its decisions.

The first workshop in the Risk Management series was held June 15-16, 1999, and addressed information needs for risk management. Proposals for several risk-management paradigms were examined to determine how better to frame the process. Participants at the workshop found that risk management is not a uniform process across the Agency. EPA's role as a decision-maker is often dependent on differences in the enabling legislation for the various EPA regulatory and research programs. Risk assessment plays a strong role in risk management decision-making; however, many additional factors are considered in making decisions. These factors include: transaction costs and research burdens associated with decisions, issues of fairness, enforceability of decisions, economic considerations, and technological feasibility.

The risk assessment-risk management process, and indeed the decision-making process as a whole, is usually not linear. Instead, decisions must often be made at times when EPA lacks a complete understanding of risks and other factors. Participants in the workshop series will continue to examine a variety of proposals for risk-management frameworks. The strengths of each will be combined into a consensus framework, to the extent possible, that is case-dependent, flexible, and simple.

Perhaps the most important finding of the first workshop was that open communication throughout the risk management decision-making process is key to its success. As a result, this second workshop examines communication between the risk manager and risk assessor, as well as between the risk manager and stakeholders.

2.0 Communication Between the Risk Assessor and the Risk Manager

The first day of the workshop focused on communication between the risk assessor and the risk manager. Through presentations and breakout sessions, participants sought to identify the issues particular to both positions and how the risk assessor and risk manager can most effectively work together throughout the risk-management process.

2.1 Perspectives on Internal Communication

2.1.1 The Role of Risk Assessment in the Risk-Management Process (Plenary Discussion)

Risk assessment plays a very important role in the risk-management process. However, decision-making does not hinge on the risk assessment alone. Whereas the risk assessment serves to define the problem, the risk-management decision itself also requires consideration of other factors, such as economics. Because of the technical nature of the risk assessment, it is often falsely assumed to be more complicated than it is. In addition, since risk assessments depend on the quality of the data input, as well as the level of conservativeness in such inputs, some risk managers are distrustful of risk assessments. Rather than accepting a good, low-cost solution based on risk alone, a risk manager may assume that the solution is not sufficiently protective because of its low cost. Finally, risk assessments are not always definitive, but often require the judgment of the risk manager in making a decision.

Some in EPA are currently considering whether risk-*assessment* information needs should be considered separately from other information used in the risk-management process. While separation may not be feasible, it is important to remember that risk assessment is only one factor in the risk-management process. Risk assessment is often the focus of attention, because it is the part of the risk-management process that is based on scientific data. Many people trust such information more than other subjective considerations. Because of this, a quantitative basis for decisions may be sought even if a decision has been based on other factors.

Risk data obtained through the risk-assessment process are also important, because all of EPA's enabling legislation, with two exceptions, requires the improvement of health as a primary basis for decision-making. Only the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) require EPA to consider cost in its decision-making process. Decision making based on health alone places risk assessment at the center of the decision, although the reality of decision making at EPA is that other factors are also important.

2.1.2 Communication between the Risk Assessor and Risk Manager (Plenary Discussion)

Participants were asked to consider communication between risk assessors and risk managers in their own offices and comment based on the following questions:

- In your program, how do risk assessors and risk managers communicate throughout the decision-making process?

- At what points in the process do they communicate?
- What kinds of critical information are elicited from this communication?
- Do communication breakdowns occur? If so, why? If not, how are they avoided?

In many cases, communication between risk managers and risk assessors works well if the risk assessor is included on the risk-management team from the beginning. Continuity and trust among staff members makes decision-making at the staff level more successful. However, when decisions are raised to a higher management level, political considerations and second-guessing of staff decisions can pose a problem. One factor that impedes good communication between the risk assessor and the risk manager is time pressures. Time constraints placed on the risk assessor can make complex work and responsiveness difficult and may cause an increased reliance on contractors. Likewise, a risk manager can also be under time constraints, such as statutory mandates or political pressures. These issues may be unfamiliar to the risk assessor.

In an office with few risk assessors and many competing priorities, a risk manager may find difficulty gaining the attention of the risk assessor. As a result, the risk manager may be forced to work directly with a contractor, even though he or she may lack the technical background necessary to properly oversee the work. This appears to be a particular problem for smaller sites; risk assessors are generally assigned to work on larger, more problematic sites, leaving the risk managers for smaller sites to take on more of the technical, risk assessment work themselves. As a consequence, risk managers for the smaller sites are left with less time to concentrate on the other aspects of risk management.

The best risk-management outcomes occur when the risk assessor and risk manager can work together from the beginning of a project before stakeholders enter the process. The risk manager uses the expertise of the risk assessor to create and evaluate different risk scenarios, rather than involving the risk assessor only at the point of examining data. This can help focus the work of the risk manager on those risks that seem potentially significant and the risk assessor can obtain an idea of the mitigating factors that may make one potential risk factor more or less important than another. By an early examination of the existence of useable data and the analysis of detection limits, the risk assessor can help the risk manager design the entire site investigation.

2.1.3 Criteria for Successful Communication (Plenary Discussion)

Participants discussed a number of criteria for the success or breakdown of communication between the risk manager and risk assessor. (See Appendix D for a transcription of the flip chart prepared during the plenary session.) In general, it is vital to consider risk assessment as one of many drivers for risk management, but one that attracts much attention. In order to make and then explain or defend a decision, the risk manager must have a full understanding of the risk assessment. In order to ensure that the risk assessment addresses the problems and issues faced by the risk manager, it is vital that the risk assessor understand the context in which the risk manager is working.

The risk assessor and risk manager must come together at the beginning of the risk-management process to discuss the goals of the process as well as any time constraints, either in the form of statutory requirements or workload. Doing so will increase trust and commitment among team members. Risk assessors must know the context of their work and understand that, although a risk assessment might ideally continue until a problem is solved, this is not possible under the time lines set by statute. In addition, through an awareness of the time frame and budget for an assessment or decision, the risk assessor will be able to describe the potential limits on data collection and analysis. These limits may serve either to focus the assessment or to indicate its likelihood of success. By an early discussion of the problem and its context, the team can anticipate criticisms of the risk assessment and understand what stakeholders will be looking for from the assessment. This early involvement must be considered, however, as an addition to the risk assessor's already heavy workload.

Specific goals of a project should be discussed. For example, the goal may be to clean up the site, but what pollutant levels would be considered 'clean'? How much uncertainty is acceptable? How conservative should the risk estimate be? Risk managers must understand that the amount of money devoted to a risk assessment will determine the level of data which can be obtained and therefore the level of uncertainty associated with the analysis. Communication throughout the process allows for refocusing of resources on identified concerns, either those with a technical basis, as identified by the risk assessor, or those with a non-technical basis, as identified by the risk manager.

It is important for scientists to be without bias and not to use inputs deliberately that would make the outcome of an assessment support a pre-determined decision. While a risk assessor should be aware of the context of his or her work, it is important to separate political influences from risk assessment outcomes. Some participants felt that because the outcome of a risk assessment depends on the data entered at the beginning, there exists the potential for risk managers to make a decision and then ask the risk assessor to use the data or levels of uncertainty that support the decision. Doing so could create mistrust between the risk assessor, who wishes to protect public health based on the risk assessment, and the risk manager, who must also consider other factors. Not only is this a potential conflict within EPA, it is also a concern among Congress and lobbyists, which often accuse EPA of using risk assessment to support already-existing decisions.

Although the risk manager should not attempt to fit the risk assessment to his or her decision, it is also important for the risk manager to know as soon as possible the direction the assessment is taking. This will allow the risk manager to begin to consider the challenges that will be associated with a particular decision. For this reason, it is helpful for the risk manager to have an estimate of the risk assessment before it is completed. Screening out some sources or pollutants early in the risk assessment stage can focus the assessment and allow it to be truly helpful for the decision which must be made. Consideration of different scenarios is done for more complex, larger-scale risk assessments, in which data are not collected for each source and assessments are based on estimates and hypothetical scenarios.

Determining the type of data to use in a risk assessment will affect the outcome. The use of defaults or estimates tends to result in a more conservative risk estimate than the use of site-

specific data. Risk managers are reluctant to accept a risk assessment that shows that less cleanup is necessary than the risk manager believes is acceptable, based on cleanup levels that were set using estimates rather than site-specific data. On the other hand, the risk assessor, as a scientist, believes that the truth is found only in the data. However, risk managers sometimes find risk assessments based on assumptions that are too conservative for a process in which decisions must be made based, at least in part, on subjective considerations.

2.1.4 A Regional Perspective on Risk Management (Bill Murray - Region 8)

Two cases from the Region 8 Superfund program were presented. The first involved the Summitville gold mine in Colorado. The mine had been operating cyanide leaching technology without a discharge permit. The firm then went bankrupt. Meanwhile, rainfall levels had been underestimated and leachate run-off flowed towards the river. In 1994, the site was registered on the National Priorities List (NPL) and was stabilized so outflows did not occur. EPA did not include toxicologists on the initial risk-management team and a risk assessment was not performed before $85 million was spent on remedial work. A human-health risk assessment was then attempted and previously gathered data were found to be useless. The ecological risk assessment was also delayed. As a result, the community downstream of the site lost respect for EPA.

The second case was at the Murray lead smelter in Utah. Arsenic and lead in soil and water were of concern and this site was proposed for listing on the NPL. The following nine criteria for risk management at Superfund sites were considered:

- Threshold Criteria:
  - Overall protection of human health and the environment
  - Compliance with applicable or relevant and appropriate requirements

- Primary Balancing Criteria:
  - Long-term effectiveness
  - Reduction of toxicity, mobility and volume
  - Short-term effectiveness
  - Implementability
  - Cost

- Modifying Criteria:
  - State acceptance
  - Community acceptance

The site team was established early and included both the risk assessor and risk manager. The community was also involved from the beginning and was shown a conceptual model of the process and the site. A stakeholder working group was established to develop alternatives for future land use. A toxicologist was available at all public meetings to explain technical issues. At this time, remedial action is underway. However, the Utah Department of Environmental Quality is not pleased with the management decision, wishing the Federal government to pay for the most extensive cleanup possible, despite the fact that the risk levels do not support such action.

The importance of involving the risk assessor at the beginning of the risk-management process has been emphasized. However, the risk assessor should also be involved during the post-decision review process, which for many programs is required after five years. During this review, EPA evaluates the effectiveness of the decision. The same considerations that applied during the initial decision-making process remain important during the review process.

One aspect of communication is trust in the objectivity of a risk assessor. In Regional and program offices with few risk assessors, generation of the risk numbers may depend on one person rather than a team. Since the risk assessment process takes place in the public eye and is not separated from the risk-management process, the potential for bias exists. A risk assessor often spends time at a problem site and may have his or her own opinion on the correct solution. The style of analysis chosen, the uncertainties accepted, the level of conservativeness, and the use of estimates or site-specific data are choices made by the risk assessor that can affect the outcome of the risk assessment. These choices are based on the professional judgment of the risk assessor; this judgment must be trusted by the risk manager as well as by stakeholders. The risk manager must then interpret the resulting risk numbers and make a decision. It has been suggested that risk assessments undergo peer review to build confidence in the assessment.

The risk assessor looks to the data to determine risks. While the risk assessor might wish to base a decision solely on objective data, this is not always possible for the risk manager. For example, stakeholders desiring the most extensive cleanup that can be had may be in conflict with the needs of other stakeholders, who feel that the incremental risk reduction may not be worth the resources that must be expended. At other times, what might be a good solution from the perspective of risk may not be acceptable to stakeholders. In an example from the Murray lead smelter case and others, some stakeholders would not accept a solution as "safe," even though the technical risk assessment showed that it was.

In summary, a risk manager must consider issues of cost, public perception and acceptance, and legal limitations, as well as risk, in making a decision. In some cases, these considerations may take precedence over risk, especially in situations in which science is not yet capable of providing a risk estimate devoid of great uncertainty.

2.2 Planning and Scoping for Risk Managers and Assessors (Ed Bender - ORD/OSP)

The risk manager uses risk assessment to guide the risk management decision-making process, from problem formulation to analysis to risk characterization. Planning and scoping for both the risk-management and risk-assessment processes ensure that the risk assessment work is relevant to the decision that must be made. During planning and scoping of the risk assessment, technical issues such as the presence of risk drivers should be addressed, but other factors related to the context of the decision, including economics, legal questions, and social analysis, should also be discussed. Stakeholder input may not directly affect the risk assessment itself, but it does influence the risk-management decision. Because the purpose of the risk assessment is to inform that decision, stakeholders do have an indirect relationship with the risk assessment.

Existing guidance on cumulative risk and ecological risk assessments focuses on planning and scoping and can be used for risk assessments supporting risk-management decisions. Other EPA workshops on cumulative risk have divided the planning and scoping process into the following five steps:

- Discuss why the assessment is needed. It is important for both the risk manager and risk assessor to understand the problem that requires a solution or a decision. The risk-management objective serves to orient the discussion about the risk assessment.

- Define the scope of the effort. Not only should the team brainstorm to determine the stressors and other technical factors to be addressed in the risk assessment, but the team should also discuss the particular remedial options that the risk manager is considering. How much of what type of data is required to decide among these options? How much budget or management support is available for the assessment?

- Determine the context (what factors will be included/excluded?). The context of a problem will give an idea of which risk-management options will be politically acceptable, and how much difficulty will be encountered if a particular option is selected.

- Develop a conceptual model. This model should show the relationship between the stressor/pollutant and the endpoint of concern, tracking it through the environment to the receptor. This step involves brainstorming, screening out factors of less concern, and understanding what type of data are available for each stressor.

- Formulate the problem and analysis plan for the assessment. The analysis plan links planning and scoping to the assessment itself. It serves to highlight priorities for the risk assessment, so that it informs the decision that has to be made by the risk manager. The consequences of missing data should be discussed, as well as potential sources of surrogate data outside the Agency.

The process outlined above is not linear but allows for brainstorming about different scenarios. It also provides the flexibility necessary to decrease the focus on one factor and move on to another, if necessary. Some factors simply will not be considered because of legal, cost, or political constraints, so time and resources should not be wasted on them. Finally, it is important to document the decision-making process so that those evaluating a decision later will understand how it was made. Doing so assists senior management in addressing questions about the decision and facilitates future evaluation.

2.3 Case Study Presentations - Communication Issues

2.3.1 Pownal Tannery Superfund Site (Leslie McVickar - Office of Solid Waste and Emergency Response)

In 1998, EPA listed the Pownal Tannery in North Pownal, Vermont as a Superfund site. While a human health risk screening (performed in support of an ongoing non-time critical removal action) did not exceed the level of concern typically used to place a site on the NPL, other information unrelated to the risk assessment weighed heavily in the decision to act. The Emergency Cost Evaluation Analysis protocol was used, which provided more flexibility than the Superfund criteria. Contaminant threats included metals, semi-volatile organic compounds, and dioxin in ground water, soil, sludge, and building materials. While data showed that the site had not adversely affected the nearest residential wells, continued migration of contaminated ground water could present a future threat to human health. Using very conservative assumptions, EPA's human health risk screening indicated low risks to the most at-risk groups, including adolescent trespassers returning to the site daily and future adult employees.

During this case, data were not necessarily available for all factors that might be considered risks. In fact, some risks were simply not quantifiable, such as the physical risk from the building itself and releases from flooding or fires. Because of this, the risk manager sought to make the known risks conservative enough so as to provide protection from the non-quantifiable risks. By making conservative assumptions, lower levels of known contaminant risks were increased. The risk manager sought to make a decision based on a common-sense analysis of various scenarios as opposed to relying simply on risks demonstrated by the data. The risk manager worked with the risk assessor to ensure that the conservative assumptions remained valid. In addition, the risk assessor supported the risk manager in evaluating the technical aspects of the contractor's work and in identifying factors and applicable regulations to communicate to the contractor.

2.3.2 Phosphide Fumigants (Mark Hartman - OPP)

Within the Office of Pesticide Programs (OPP), the risk manager is considered the leader of a team working towards a regulatory decision. It is necessary to coordinate interdependent efforts of the team (such as the results of those examining exposures from different media), fulfill information needs and data requirements, maintain the project schedule, set priorities, communicate with management, and develop a mitigation strategy. The risk assessor works with the risk manager to enhance his or her understanding of risk and other science issues, while the risk manager communicates policy issues to the risk assessor. Communication begins at the team kick off meeting and continues through the development of the risk assessment, the development of the mitigation strategies, and the regulatory decisions.

EPA is required by FIFRA to reregister pesticides, including aluminum and magnesium phosphide, that were originally registered before November 1, 1984 to ensure that they meet today's more stringent safety standards. Registration of a pesticide is a scientific, legal, and administrative process through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. EPA assesses a wide variety of potential human health and environmental effects associated with product use.

The reregistration process for aluminum and magnesium phosphide began with several potential problem areas. The risk manager in charge was about to leave EPA and the risk assessor

was newly hired. Other turnover of key players increased the pressure to complete the product review while removing some of the expertise to do so. In addition, the industry stakeholders were smaller companies who were not familiar with the applicable regulations and had no experience with the process. Finally, EPA was attempting to use a new approach utilizing greater stakeholder involvement in the process.

The risk-management team responsible for this project sought to ensure its success. The team accepted the fact that they had to flatten their learning curve by working together and strategizing with many minds to determine a successful approach. They also recognized the importance of educating industry. By maintaining open, honest, consistent, and two-way communication, the team was successful in its efforts. While a natural dichotomy exists between the risk assessor and risk manager, as it exists between science and policy, it is vital that the two work together as a team.

Without successful communication, the team might have failed to meet its milestones. It would have been faced with reworking its assessments, since the science provided by the risk assessor would not have matched the needs of the risk manager. The team would not have been able to inform its management of project progress correctly. Ultimately, these problems would have led to a poor decision.

2.4 Risk-Management Information Models (Hugh McKinnon - ORD)

Risk assessment guidance has existed since 1983, when the first guideline from the National Academy of Sciences was published. The process follows these four steps: (1) identification of a hazard; (2) assessment of the dose-response relationship; (3) assessment of exposure; and (4) characterization of risk. A similar framework for risk management has been developed. A model developed by the National Research Council in 1996 follows an iterative process with analysis and feedback throughout. Other groups, including ORD, have also created models depicting the process (see Appendix C). These models attempt to show the types of information needed to reduce uncertainty in the risk-management process. The models tend to lack an evaluation component, which will become increasingly necessary as the Agency attempts to demonstrate its GPRA goals.

The data needs identified in the risk-management model cover a wide range of areas, many of which are outside of EPA's traditional expertise. ORD is considering building up social science expertise, such as economists, to provide support to program offices. ORD is also undertaking a series of pilot programs to examine risk-management options and predict effectiveness and cost for four areas: (1) endocrine disruptors; (2) fine particulate matter; (3) arsenic in drinking water; and (4) *Pfisteria.*

2.4.1 Breakout Exercise - Communication During Planning and Scoping

Participants were divided into three groups for this exercise. Each group was asked to discuss the risk management/risk assessment communication process and develop a set of principles for what should be done or avoided, from the perspective of communication, to aid the

process. Summaries of each group's work are presented below; transcripts of flip charts prepared during the sessions are given in Appendix D.

Breakout Group 1

Group 1 first differentiated between external and internal risk-management communications. Communication with stakeholders is considered external, while the dialogue between the risk assessor and risk manager is an internal process. Group discussion examined three aspects of this internal communication process:

- Defining risk-management project roles and qualifications
- Creating project teams
- Using documentation to ensure risk-management communications

To create a structure to ensure successful communication during the risk assessment, the role and qualifications of the risk assessor should be defined during initial project planning. For example, risk assessors may be trained as toxicologists, statisticians, or those with other areas of expertise. Their view and interpretation of information will likewise vary based on their educational background. Risk managers must understand the limitations or qualifications of the risk assessor to be able to use and present assessment information credibly.

The risk assessor must know the full context of risk-management decisions and understand that the role of the risk manager includes attending to socioeconomic considerations as well as to scientific data. The risk assessor must be kept involved in the process as decisions are made. The risk assessor can provide clarification of assessment details, support the interpretation of information for decision-making, and help refocus the effort if necessary.

Currently within EPA, however, risk assessors are not available for additional input during risk management decision-making, because project resources are reassigned to the next risk assessment. One way to ensure that project resources are available for the duration of decision-making is to create permanent project teams. Permanent project teams would support a feeling of project ownership and would provide continuity and clear accountability. Training programs should be structured so that, at a minimum, risk assessors and risk managers are trained together. If possible, all risk-management project team members could train together to ensure that methods are defined, roles understood, and the many kinds of information that are factored into a risk-management decision are communicated.

A second step to ensure good communications between the risk assessor and the risk manager is to identify areas in which the information needed by a project's risk assessor and risk manager overlap. The focus should be on what information both need to know and what information must be documented for use by future risk managers and others, such as new employees, who will be trained to work on projects.

A formal documentation process, which describes the rationale behind risk-management decisions, is needed to capture lessons learned during project work, provide a solid basis for

defending risk-management decisions, and record the existence of special circumstances which were used in the decision-making process, thus minimizing the possibility of the decision being considered a precedent.

Decision trees offer one form of graphic documentation that can be used both to structure and to record project choices. Additionally, decision trees clearly present the uncertainties contained within the decision-making process. Because decision trees are not widely used in risk management at this time, cultural change must be initiated within the Agency.

Since many risk assessments must be made within short time frames, any documentation process created should be supported administratively and be easy to implement. Existing Agency formats could be used and adapted for this purpose. All documentation should work toward clarifying project issues, since one of the major goals of communication is ensuring that all those involved understand the issues in the same way.

A method of ensuring the accuracy of communication between the risk assessor and the risk manager is to build feedback loops, or communication milestones, into the process. Communications should involve a follow-up step in which receipt of any information is confirmed. After the information is used, the communication process should involve some kind of debriefing step in which the risk assessor and risk manager can evaluate if their actions worked toward furthering project goals.

Breakout Group 2

The group began by laying out the decision-making process as a whole. It includes the following steps:

- Identifying the problem
- Planning and scoping
- Analyzing factors
- Considering management options and transaction costs
- Making the decision
- Evaluating the decision

Transaction costs include the potential loss of political capital resulting from a decision; a particular solution may be achievable in the case at hand, but the overall effect on the entire program may be detrimental.

Preliminary and detailed planning and scoping is an iterative process. It includes bounding what will and will not be accomplished, based on legal, statutory, resource, stakeholder, and other concerns. A clear explanation of what will not be accomplished is important, not only for maintaining trust with stakeholders but also for highlighting potential gaps that might be addressed by others. Finally, creation of a conceptual model during scoping will help the risk-management team plan the rest of the process.

The group then considered factors in the process, such as the risk assessment for a health or ecological exposure; prioritization of risk; selection of endpoints; identification of management goals for the entire EPA program and for the specific case under consideration; the cost effectiveness of the decision (whether a remedy or regulation); stakeholder involvement; technical feasibility; political feasibility; legal issues; State acceptance; and risk-management options.

The group attempted to place each factor into the process, but concluded that most factors required different levels of consideration at many points throughout the process. This demonstrated the iterative nature of the process. For example, stakeholder involvement is important in all parts of the process in order to make it transparent. However, there are points in the process at which each type of stakeholder can best be involved. Not all stakeholders have the scientific background to contribute to the more technical aspects of the discussion, but should be involved in making decisions based on science.

The group then considered communication aspects involved with these factors. It was decided that communication needs are similar for all factors; therefore, the group chose to consider risk assessment in particular. The group identified who was involved in the assessment, when they should be involved, and what their involvement should be.

Risk assessors, as stated throughout the workshop, must be involved in the process and communicate with the risk manager. This should occur "early and often," depending on the level of the risk assessment, the resources available, the level of trust, and organization policy. An important role of the risk assessor is to educate the risk manager. Participants felt that the Agency currently hires young, non-technical people and expects them to perform the job of risk management without training. New hires should receive an initial orientation to familiarize them with the work of all the different parts of EPA. They should be connected with those who have more experience within the Agency. Stakeholders must also be involved in the process from the beginning, but their level of involvement depends on the stages of the process, among other factors.

Breakout Group 3

This group focused on developing a sample process as well. They determined that it is important to build the team early, identify stakeholders, provide basic information on the issues, and define the goals for both the risk-assessment and risk-management processes. In addition, applicable regulations, legal requirements, and potential obstacles to the process, both technical and political, must be identified early. They emphasized that all members of the team must understand the complexity of the process.

A regional representative provided information on how the process actually looks to those involved. The framework of the process appears simpler in application than the discussions make it seem. Also, in practice, there is a greater awareness of an overall schedule of projects and the teams responsible for them. It is important to remember that the risk-management process does not represent the first involvement with a site, but rather occurs after significant and useful preliminary work has been done, often by a site assessment team.

An important consequence of this prior work is the existence of available and potentially useful data. In many cases, these data contribute to how the risk manager sets priorities and directs the initial stages of the process.

The usefulness of existing data to aid in the creation of a conceptual model and identify preliminary options must be balanced with the need for a risk assessment to be completed before determining remedial options. In trying to navigate this tension, the group discussed both the uses of a conceptual model and the values of iteration. The conceptual model was seen in one sense as helping team members understand the process beyond their individual perspectives. However, most were wary of a model that would define the process too strictly before the data were received from the risk assessors.

In practice, this problem is solved by maintaining communication and interaction within the steps of the process. Therefore, risk assessors do not simply receive assignments and return with a final result. Rather, there is a system of review of interim deliverables, which creates a forum for the risk manager to inform the risk assessors of changing priorities and to negotiate additional data needs. The iterative process provides a mechanism to revisit assumptions based on new data, such as new exposure scenarios. In this sense, the conceptual model serves both as an early framework and as a tool to manage the products of the iterative process.

Once the goals of the process are set, the risk assessor can work with the risk manager to determine the amount and quality of data necessary to meet those goals. In addition, the resources necessary to obtain and analyze the data must be estimated. When the scope of the effort is known, team members can set up a schedule for the risk assessment and review process. Review throughout the risk-assessment process is important so that the risk manager can anticipate the outcome and the assessment can be focused on the most important aspects of a problem. The risk manager can identify potential scenarios and a preliminary risk analysis can be performed. Such screening should be done before completing a full risk assessment on factors that are not important. Flexibility must be built into the process to address changing needs identified during the preliminary stages of the assessment.

Plenary Discussion

During the plenary discussion following the breakout groups, the point was raised that potential exists for conflict between the engineer and the risk assessor. Engineers do not see the value in assessing risk in cases in which the best available technology is already being used. However, risk assessment in such cases can point out potential problems requiring an engineering solution. Risk can be considered in conjunction with technical limitations in the following four ways: (1) if there is a low risk and control technology exists, it should be used if cost effective; (2) if there is a low risk and no technology exists, nothing needs to be done; (3) if there is a high risk but technology does not exist, it should be developed; and (4) if there is a high risk and technology exists, it should be used.

The group agreed on several factors involved in enhancing communication between the risk assessor and risk manager. The first is assembling the entire team, including the risk assessor, early and setting project goals, perhaps using a conceptual model to ensure that all

understand their roles in the context of the project. Initial scoping and planning must address identifying key stakeholders, legal requirements, project time line, and data-quality requirements. Continuous communication is necessary throughout the process. Risk assessors should provide preliminary findings to the risk manager so that priorities for the risk assessment might be refined as necessary. This will also allow the risk manager to define potential options and begin to evaluate them.

2.4.2 Technical Innovation Support (Deanna Crumbling - TIO)

The EPA Technology Innovation Office (TIO) works to move innovations for the characterization and remediation of hazardous waste streams into common practice, particularly in the Superfund and Resource Conservation and Recovery Act (RCRA) programs. Of particular interest to the risk manager is Field Analytical Technology, which is becoming easier to use and may be able to provide data in support of risk assessment. The technology should be combined with planning methods to increase its efficiency, in a process called Technical Project Planning. While this process requires more resources at the beginning, the end result is more likely to be acceptable. Less resources for redoing work that was unnecessary means cost savings over the long run. TIO has created a training program for Superfund remedial project managers and their management, although modules will be created.for use at the staff level. The 4 ½-day course covers project strategy and Field Analytical Technology.

A software system, called Spatial Analysis and Decision Assistance, has been created by the University of Tennessee and is in the beta-testing phase. Once data are entered, the system plots boundary maps and determines uncertainties for different risk levels. The system can assist investigators in identifying sample locations that will be most helpful in reducing uncertainties. The program will be available through the Internet. TIO seeks input from EPA staff on potential applications of the software and other modules it should include.

Workshop participants pointed out that there is a misperception within Agency management as to which systems and protocols are usable. They suggested that TIO meet with staff throughout the Agency program offices to address obstacles to the use of new technology. TIO should focus its outreach on mid- to upper-level management rather than on staff members, who are interested in the tools but not permitted to use them.

2.5 Risk Assessor - Risk Manager Collaboration on Five Watershed Assessments (Victor Serveiss - ORD)

Risk management through a watershed approach requires merging environmental science and ecological risk assessment with public policy. A variety of factors enter into decision-making, including social and cultural factors, legal mandates, political considerations, economics, historical precedence, and ecological risk. Watershed assessments were conducted at five demonstration sites around the country (Waquoit Bay, Massachusetts; Clinch Valley, Virginia; Middle Platte River, Nebraska; Mid-Snake River, Idaho; and Big Darby Creek, Ohio). Risk-assessment and risk-management teams were created for each site. Risk-assessment teams included universities and research centers in the region, contractors, EPA Headquarters and Regional offices, and other Federal agencies. Risk-management teams included some of the same

research centers, non-profit environmental groups, farmers, and local, State, and Federal government entities.

Risk-management goals for watersheds are not as clear as those addressing only health concerns. For example, reduction of certain pollutants can be traced directly to increased cancer incidence in a population, while the effects of pollution in a watershed are less obvious. Traditional risk assessments are not appropriate for determining effects on a watershed. Instead, cumulative risk assessments are required in order to examine multiple stressors. For example, to understand the effects of a mine on a watershed, the risk assessment must consider a variety of stressors, including sediments, excess nutrients, and chemicals. Because cumulative risk assessment is a complex process, it is important for the risk assessor to work with the risk manager to determine from the start what resources and budget would be required to obtain meaningful results.

The process for risk management for geographical settings should begin with a clear goal and definition of the scope of the risk assessment. A conceptual model of the process, outlining ecological effects and measurements, should be developed. Such a model might flow from identifying the source, stressor, response, and finally a measurable change. Such models are powerful communication tools, in that they illustrate the link between human activities and ecological effects. They facilitate understanding multiple stressors, pathways, and the watershed approach. However, it is important to maintain flexibility as multiple issues arise and the focus of the effort changes.

In the case of watersheds, the current regulatory authority of EPA is not necessarily clear. Therefore, the result of the cumulative risk assessment may not be a regulatory decision by EPA. Instead, EPA will seek to point the problem out to those who can take action, including State and local authorities as well as other stakeholders. In these cases, the role of the EPA risk manager might be to simplify the technical aspects of the assessment for the stakeholder audience and provide suggestions of risk-management options. It is particularly necessary, then, for those stakeholders to understand what will, and what will not, result from the risk assessment.

In the case of watersheds, and other times in which EPA does not have clear regulatory authority, it is the stakeholders who are the true "risk managers" because it is they who can take action. For example, in the case of non-point source pollution from farm runoff, EPA can identify the problem and provide suggestions for best-management practices. However, it is the farmers themselves who, in the absence of regulations, must decide to implement them. It becomes part of EPA's job to help these "risk managers" understand the situation and address it.

2.6 Day 1 Wrap-Up

At the end of the first day, workshop participants were asked to consider key points they would wish to convey to the EPA Administrator regarding the Agency's focus on communication in the risk-management process. The most important of these points is that communication between the risk assessor and the risk manager must occur early, often, and continue throughout the process. Other participant perspectives include:

- Sufficient risk-assessment capability, in the form of staff and money, to provide quality information to the risk manager in a useful format does not currently exist at EPA.

- Early interaction between the risk assessor and risk manager is necessary and must be institutionalized so that the connection remains strong throughout the process.

- Communication between the risk assessor and risk manager does not simply involve keeping each informed during the process, but rather clarifying information and actually working together to solve a problem in a scientifically- and politically-acceptable method.

- New, junior-level employees are expected to enter the risk-management process without first receiving any form of guidance, orientation, or explanation of the resources available at the Agency or the benefit of others' experience. An orientation or training session is necessary so that all members of the team begin the risk-management process with the same understanding.

- The risk manager and risk assessor must both be educated in all aspects of the risk-management process so that they can understand the information they receive from one another.

- Different stages of the risk-management process should be documented, making it easier for newcomers to the team to understand what has occurred and also to help explain decisions to management or to those who might question them.

- No single person can know everything about risk management. Cross-disciplinary understanding is necessary, perhaps through mutual education.

- It is necessary to have a general plan or model for risk management, which creates a system that all parties agree to and lays out the expectations for all team members.

- At this time, in some programs risk managers and risk assessors are evaluated differently, which gives them different perspectives of success. For example, a risk-management decision may be made that does not involve action, such as deciding that the level of risk for a particular problem is not sufficient to warrant remediation. On the other hand, a risk assessor will receive credit for registering a chemical, but not for sending a chemical back for further development without registering it, although this is also a valuable action.

- The risk-assessment process should be used to support the evaluation of risk-management options. For example, the risk manager should be able to discuss "what-if" scenarios with the risk assessor from an early point in the process to

screen out factors of low importance and understand which risk-management options would have the greatest benefit.

- Flexibility must be built into the process. The iterative nature of risk management means that new information will be added, as the process progresses, both on the risk-assessment and decision-making levels.

3.0 Stakeholder Involvement

3.1 Introduction (Hugh McKinnon - ORD)

EPA's Stakeholder Involvement Action Plan, published December 1, 1998, outlines actions EPA intends to take in order to increase opportunities for, and the quality of, stakeholder involvement in its regulatory and non-regulatory programs. This Plan is available on EPA's web site at http://www.epa.gov/stakeholders/siap1298.htm. EPA is continuing to consider improvements to its process of including stakeholders in the Agency's activities. Several opportunities to examine such issues exist, including the EPA-wide Community Involvement Conference, scheduled for August 1999 in San Francisco.

The second day of the risk-management workshop examined communication with stakeholders during the risk-management process. Participants were asked to consider issues involved with stakeholder communication at EPA (see flip chart transcription in Appendix D). Their comments are summarized below:

- EPA staff may be involved in negotiations with stakeholders and across offices and believe that agreement has been reached. However, the project fails when stakeholders then contact EPA upper-level management directly, who then change the agreement without ever considering, or possibly even being aware of, the negotiations that were occurring. This puts the authority of the staff to conduct such negotiations into question and seriously harms staff morale. EPA staff feel that they lack the authority to negotiate, and, when they do so, they are not supported by their management

- Communication during negotiation must involve more than simply having each participant share their preconceived ideas. Communication requires an effort to understand the issues of concern to each participant and to understand that compromise is required.

- Stakeholders must be brought together in an organized fashion, knowing which issues are available for negotiation and which are not. Stakeholders sometimes presume that all points of view will be accommodated, which is not possible. When such stakeholders find that their input was not reflected in the final decision, the communication process may have built more opposition than consensus.

- It is important to establish rapport with stakeholders. EPA risk managers should understand their issues of concern, including those on which they can negotiate and those which are fixed. All stakeholders, including those who are less vocal, should be considered. Discussions should be limited so that vested interests and those unrelated to the question at hand do not take over the process.

- EPA must make a conscious effort to involve the affected stakeholders themselves, and not simply their representatives. For example, industry trade

association staff may not really understand the issues faced by their members at the facility level. The members themselves may be interested in some of the solutions proposed by EPA, which may have been automatically rejected by the association staff.

- Projects requiring stakeholder involvement do not always have a specific problem to be addressed by EPA. Instead, EPA could be working to help local groups help themselves. For example, in the Recycling Superfund Sites Initiative, EPA is facilitating projects to determine the use of remediated Superfund sites for future uses.

- Stakeholder involvement must be maintained throughout the process. At the same time, it should be meaningful rather than done simply because it is required. Active involvement of stakeholders requires more than simply mailing announcements or placing notices in the newspaper.

- The public must be assisted in understanding technical issues. Many problems arise because members of the public are frustrated during discussions because they do not have an understanding of what is possible. When they do not understand, the public often believes that EPA is hiding information and will therefore oppose the Agency's work. EPA representatives at public meetings must be able to communicate the technical information clearly to avoid misplaced anger resulting from ignorance. Technical assistance grants also help local organizations understand the technical issues so that they can participate in a meaningful way.

3.2 Opportunities for Stakeholder Input (Deborah Dalton - Office of Policy and Reinvention)

Stakeholder involvement is mandated by several regulations and Executive Orders. There are several categories of stakeholders: (1) parties who directly implement the rule; (2) State and local co-regulators; (3) parties necessary to implement certain provisions of the rule; and (4) parties who can block implementation of the rule.

Those who design stakeholder involvement should, above all, be clear about what role the stakeholders will play in the process. It is important to specify whether they will be participating in the actual decision-making or limited to providing input to inform a decision made by EPA. Misunderstanding in this respect can result in stakeholders feeling betrayed that their input was not used. EPA management must also understand the role of stakeholders in a particular situation.

Three types of stakeholder roles exist. The first is information exchange, in which opinions, generally of individual stakeholders rather than their representatives or associations, are solicited. The second is using stakeholders to provide recommendations in an effort to reach consensus. However, EPA is not committed to implementing these recommendations. The third is joint decision-making, in which EPA and outside parties negotiate a rule or enforcement settlement.

Including the correct stakeholders is important. The risk manager should consider potential stakeholders with respect to the knowledge and constituency they bring to the process. Is it necessary that they participate in reaching an agreement? Who will support or oppose the risk-management options under consideration? Known parties to the process should be asked for suggestions.

Stakeholders can be found in many forms. Members of the general public can be stakeholders, but they are often difficult to involve because they are not organized. Associations can provide a useful starting place for locating stakeholders for a particular issue. However, it is important to know the range of membership in a particular association. For example, in some cases it might be useful to involve industry representatives from both large and small companies rather than simply one association staff person. In addition, associations may send their outside counsel to a negotiating session, rather than someone actually involved in the industry. This counsel may have the agendas of other related clients in mind and will most likely not have the same understanding of the technical capabilities of the industry as an actual company representative.

During a negotiation session, stakeholder representatives often form caucuses of allied interests. The actual negotiation takes place in between meetings and during breaks; discussions at the table serve to ratify what has been decided during the caucuses. The decisions of the representatives may be called into question by their constituents if they feel that they were not consulted. For this reason, it is important to extend involvement, if only at the level of notification, to members of the public and the media. In addition, representatives must be reminded and encouraged to undertake the same sort of communication process with their constituents as EPA does, although this does not always occur.

To ensure that all participants have the same understanding of what is happening in the decision-making process, brief summaries of all meetings should be prepared and provided to all participating and other interested parties. Summaries, rather than transcripts, should be used. When every word of a negotiation is recorded, it may be more difficult to obtain the compromises necessary for negotiation. It is important for participants to be able to express their ideas and positions without concern that they will be held to their suggestions. Protocols and ground rules should be set in advance. They should cover the process of negotiation itself, but should also extend to the conduct of stakeholders outside the meeting place. For example, stakeholders should agree on what they will tell the public and the media about the ongoing negotiations before an agreement is reached.

In summary, stakeholder involvement requires careful preparation. It is important to include the correct parties and determine the scope and schedule of the proceedings. Stakeholders should be given lead time to prepare their participation and coordinate their schedules and budgets with EPA. Unprepared stakeholders, who have not had an opportunity to formulate their position and points of negotiation, will reject all options automatically. Eight specific recommendations for success have been identified in a document entitled *Best Practices for Government Agencies - Guidelines for Using Collaborative Agreement-Seeking Processes*, published by the Society of Professionals in Dispute Resolution and listed below:

- An agency should first consider whether a collaborative agreement-seeking approach is appropriate.
- Stakeholders should be supportive of the process and willing and able to participate.
- Agency leaders should support the process and ensure sufficient resources to convene the process.
- An assessment should precede a collaborative agreement-seeking process.
- Ground rules should be mutually agreed upon by all participants.
- The sponsoring agency should ensure the facilitator's neutrality and accountability to all participants.
- The agency and participants should plan for implementation of the agreement from the beginning.
- Policies governing these processes should not be overly prescriptive.

3.3 Stakeholder Involvement in the Rodenticide Cluster Case (Michael McDavit - OPP)

EPA OPP decided to mitigate the potential for poisoning from pesticides included in the rodenticide cluster. The first phase of this project involved determining short-term mitigation measures; during the second phase EPA created a stakeholder workgroup to examine long-term solutions.

The workgroup consists of public interest groups, including a group involved with environmental justice concerns, as well as large and small industry stakeholders. The first two meetings of the workgroup were spent on acquainting stakeholders with one another, both professionally and personally. Members were educated on relevant issues, including the context for the workgroup as well as the problem. Only later did the workgroup begin examining mitigation options. EPA staff emphasized that the workgroup was involved in the process to generate an action plan rather than to argue over predetermined ideas. In this case, EPA was not seeking agreement from stakeholders for a decision or comments on a proposed policy but rather the creation of the decision itself.

A variety of lessons were learned regarding stakeholder communication. Stakeholder workgroups allow for a better understanding of the problem at hand and the risks. They allow for continued analysis and serve to educate the Agency, the public, and the stakeholders themselves. They provide a way to better incorporate public values into decision-making. Involvement in a workgroup is a way of making the process transparent and showing the evolution of a decision. This activity is extremely resource-intensive; however, agreement is more likely to occur without challenges and will more successfully withstand challenges that do arise.

One of the challenges with such a workgroup is to find the correct balance. For example, some stakeholders have more resources to devote to the work than others. Some, particularly public interest groups, use volunteer support and do not have the same experience of participating in this type of activity as an industry stakeholder might. In addition, these stakeholders may only be inclined to remain involved when they feel that their concerns are being addressed, although they may not have the same negotiation ability as an industry representative. It is important to ensure that no stakeholder feels that they are simply there so that EPA can say that they participated, when in reality their concerns were not even heard. Quality facilitation is necessary to maintain a balance in the workgroup by addressing bias, encouraging all who attend to participate fully, and asking participants to be open to all points of view. While it is important to be inclusive, involving members of the general public who do not have a constituency may present a problem. Experts in the field may be listened to by stakeholders, but general members of the public with uninformed issues are more likely to be ignored.

In this particular case, OPP found that the workgroup participants were accustomed to interacting in a more adversarial context. It was important for the workgroup facilitator to cultivate a non-adversarial tone to the workgroup and remind participants, particularly industry, that the process was meant to be cooperative. Likewise, it was necessary for EPA staff to allow the group to work rather than pushing for a predetermined solution, providing an atmosphere in which creative problem-solving could occur.

Before convening such a workgroup, it is necessary to set a concrete goal or mission, although the goal may change as the group works. The mission will help the group know when to end the process and will help to target discussion. This may be more important than agreeing on the actual problem. For example, in this case, industry's view of the problem of potential poisoning differed considerably from that of the environmental justice group. However, as long as a solution could be found to make poisoning less likely, it was not important to agree on the problem. It is also important that the expectations of the mission be realistic.

Sustained, sincere commitment of senior management to the workgroup is important. While the actual work can be accomplished by staff, a senior manager should attend the first meeting to show that the workgroup has support and that the staff have been delegated authority to lead. In addition, management should make it clear that difficulties must be addressed within the workgroup and that bypassing the group to reach upper management will not result in concessions. Participants should also be encouraged to bring all their ideas to the workgroup rather than seek EPA staff outside of scheduled meetings, as this undermines the collective work of the group. EPA's position in such a workgroup is balanced between acting as a facilitator and as a representative in its own right.

3.4 Breakout Exercise - Stakeholder Involvement: Consideration in the Risk-Management Models

Workshop participants were divided into three groups and asked to develop recommendations for applying the principles of stakeholder involvement discussed above to the risk-management process (identifying, planning and scoping, analyzing, making a decision, and evaluating the decision).

Breakout Group 1

The stakeholder communication process must be made a priority at the outset of a project; risk managers must plan for communication flow from the beginning. One of the first steps is to identify stakeholders, including those with a specific stake in the risk assessment, as well as in the risk-management process. This effort often reveals unexpected parties and concerns that will need to be addressed. In the Pownal Tannery Superfund Site case study, the following groups were revealed to be stakeholders in the project.

- Residents, identified through a door-to-door canvass
- Local fire-fighting authorities
- Town officials
- Children illegally trespassing on the site
- Local development commission
- State historical protection agency
- Local watershed group associated with an onsite dam
- Land owners
- Groups that wanted technical assistance
- State environmental official
- Those who paid for project work

Stakeholders who are not at the table initially can intrude on the process later and cause delays. Although this cannot be prevented, the impact of late intrusion on the process can be minimized. Stakeholder representatives who are present must communicate effectively with the groups they represent so that there are no surprise reactions late in the process. Effective communication can be accomplished through updates, phone calls, fact sheets and use of other communication methods. Project managers cannot assume that officials truly represent constituent opinions, so use of several communication avenues is a method of ensuring receipt of the desired information.

The role of stakeholders must be decided early in the process, as well as the points at which they will have an impact on decision-making. Stakeholders may simply be asked to provide input; in other cases, stakeholders will be asked to reach consensus about a decision. While stakeholder involvement is necessary throughout the process, the role of the stakeholder may change at various points. At some points, stakeholder involvement may be limited to keeping them informed. At others, stakeholder opinions may be solicited. Assigning substantive, specific tasks to stakeholders is one way to avoid confusion from participation by members whose reason for involvement is unclear. After decisions have been made, it is important to follow-up with stakeholders to let them know how their input influenced the risk-management process.

Accurately identifying local stakeholders early in the process also minimizes the impact of the involvement of national representatives. The agenda of local and national stakeholders can vary. Local representatives are directly accountable to the constituencies they represent and may have a greater motivation to achieve progress toward defined goals.

Each stakeholder in a process should be made aware of the concerns and goals of the other stakeholders in the process. All should be aware of the dimension of the effort in which they are engaged and be given an accurate assessment of the achievements that are expected and realistically possible. Risk managers can determine whether stakeholders are most productively addressed separately or collectively.

Good project documentation is useful to inform those joining the process late as well as explaining the decision in the event of challenge. Anticipating stakeholder stances is one way to gauge the type of documentation needed.

Risk managers might have to devise ways to ensure that stakeholder representation is balanced and communication is not one-sided. For example, funding may have to be found to remove obstacles to allow meetings to be attended by volunteer representatives. Grants may be necessary for some stakeholders to hire technical assistance to help them interpret technical risk assessment data.

The group summarized its discussion with the following list of requirements for establishing balanced stakeholder participation:

- With local projects, identify local stakeholders
- Develop incentives for participation and help to remove obstacles to participation
- Communicate all stakeholders' roles and boundaries of influence
- Encourage commitment to the process by asking for stakeholders to commit resources
- Cross-educate stakeholders about the goals of all others
- Follow-up on commitments and project decisions and outcomes

Breakout Group 2

Planning and scoping is one of the most essential parts of the process and the one that will affect the entire effort. It begins with the convening process, which involves determining the appropriate stakeholders, locating them, and motivating them to participate. This must occur well in advance of any action, to ensure that stakeholders have an opportunity to prepare their positions and to obtain resources. Local stakeholders can be found in community clinics, churches, libraries, and other places where people go for social interaction and information, such as community newspapers. Outreach to individual stakeholders is important to encourage attendance at stakeholder meetings and should extend beyond announcements on the Internet or in the newspaper. Parties who have been identified should be asked for suggestions about others to include, based on who their partners are as well as their adversaries with regard to the issue. Local newspaper morgues can be searched on a particular locality or company and those who are used as sources for quotes might be appropriate stakeholder representatives. Environmental Impact Statements for other projects in the area or dockets for similar rules can be examined to locate potential stakeholders. Chambers of commerce and local bar associations may have members who would be stakeholders.

The scope of the project must be determined; it is better to embark on a limited project that will be completed instead of a larger one that will never have the resources to begin. While EPA should clarify its goals, it is also necessary to ask stakeholders to identify the issues that they believe are relevant. Unanticipated issues may affect who should be included, either - expanding or contracting the pool of stakeholders. Contracting the number of stakeholders is as important as including all who should be included. If EPA is not intending to address the issues most important to a particular stakeholder, that stakeholder will lose motivation to participate and may feel that his or her time has been wasted. This could lead to difficulties with future efforts.

During planning and scoping, the time frame that corresponds to EPA's needs, whether statutory or budgetary, should be explained. In addition, involved parties should be asked for their opinion on a reasonable time frame. EPA must ensure that it has been realistic in the time and resources the Agency wishes to devote and that potential stakeholders are also willing to devote sufficient time to ensure that the objective can be accomplished. EPA should also explain the level of commitment that is expected from stakeholders, for example, whether the Agency expects stakeholders simply to provide comments or to follow the process through to the end. Stakeholders should have an expectation of the number, type, and location of all anticipated meetings. Knowing the issues of importance to particular stakeholders will help EPA understand their potential level of commitment. An initial meeting where the goal is to observe interaction and test certain ideas may help EPA to determine these issues.

Once stakeholders have been located, it is important to motivate them to participate and establish trust. For example, meeting summaries can be distributed to stakeholders even if they did not attend, or EPA can contact the stakeholder and tell them about the meeting. Stakeholders should be shown that issues of concern to them will be addressed. They must know that they do have the ability to influence the outcome and that they will be provided with the tools to participate, such as technical assistance or reimbursement of the cost associated with attendance. Stakeholder involvement should not be lost because people are intimidated by the technical content of the issue. Disparity in technical expertise among stakeholders must be addressed. EPA should attempt to identify a person associated with a stakeholder group who has the necessary expertise or else provide other methods of technical assistance. For example, grants may enable a group to hire an expert to interpret technical materials for them.

During the planning process, it is also necessary to plan for evaluation. A means of evaluation should be planned and communicated to stakeholders, then tracked throughout the process. If the evaluation hinges on availability of resources in the future, this fact should be emphasized so that stakeholders feel that EPA staff are accountable. It is also possible that someone other than EPA, such as a stakeholder group, could conduct the evaluation.

Stakeholder participation continues in the analysis stage of the risk-management process. At this point, it is important for stakeholders and EPA to know regulatory restrictions that may exist. EPA may be restricted from releasing certain data or from accepting a particular risk-management option, for example. The analysis process must be well documented, and include the issues and factors considered, sources of data, assumptions, and calculations in a format that is readable and readily available. A trusted, independent technical expert can help a stakeholder

group determine the validity of an analysis, enabling useful comment on the analysis itself and not simply the decision made. Peer review of the analysis will also help establish its validity. Rather than wait until all information has been collected and published in final report format for a long-term analysis, EPA should release progress reports periodically to allay any concerns that the Agency is taking action out of the public eye.

During the decision stage, EPA should clarify once again the level of influence the stakeholder groups will have on a particular decision, beyond the information they have provided. The person or entity who will make the final decision should be explicitly stated. Issues of contention should be outlined, as well as alternatives, particularly when no consensus has been reached. For those who have not been involved in the earlier part of the process, EPA should summarize the factors it considered in reaching a decision. If personnel turnover has occurred, EPA should reintroduce its project team and emphasize that the approach has not changed. Since many outside EPA are not familiar with Agency protocols, the general rulemaking process should be summarized.

Although EPA staff often try to adopt a neutral role in the negotiations and act as facilitator, it is important to remember that EPA is not a neutral party. The Agency has its own responsibilities and mandates based on statutes, as well as paths it cannot take. Therefore, it is necessary to have a non-EPA person run the negotiation process, if possible. EPA should also clearly state the flexibility of the decision. For example, is the decision final and not subject to change, or will it be revisited within a certain period of time? Will its implementation be phased? Will new information or factors be considered later? Is there a mechanism for evaluation?

During the evaluation stage, EPA must show the outcome of its decision and the effectiveness of the action taken. At this time, EPA must remind its stakeholders of the goals which were to be accomplished. Feedback should be sought from the stakeholders who were involved. The evaluation mechanism established during planning and scoping should be implemented, emphasizing trust and the accountability of the Agency. Technical assistance should be provided to stakeholders to evaluate the results. Finally, applicable and usable items should be continually placed in the docket for evaluation by stakeholders.

Breakout Group 3

The group began with a discussion of initiating events in the decision-making processes. Initiating events include established regulatory processes, permitting applications, internal policy review, and new public issues (such as atmospheric ozone). The nature of the initiating event itself will provide information on the scope of the process, facilitate the identification of stakeholders, and may suggest suitable approaches for their involvement. In many cases, stakeholders will agree that a particular issue is a problem and agree to work on it if EPA's response or decision will affect them materially. New environmental problems require EPA's awareness of events beyond its established practices, and appropriate stakeholders may be harder to identify. In all cases, the problem should not be stated immediately for stakeholders; instead, stakeholders should be asked to provide their own definition of the problem. In this way, EPA may gain new perspectives on the issue that the Agency had not considered previously.

The group proceeded to address the planning and scoping step of the decision-making process. Both useful approaches and typical obstacles were identified. Planning and scoping is an initial step completed internally at EPA in advance of planning and scoping with stakeholders, at which point a plan for stakeholder involvement *throughout the process* is developed. The plan can be kept flexible throughout the process by inserting a mechanism for stakeholder feedback.

It is necessary to be open and consistent with potential stakeholders with regard to their place in the process, whether it be as a provider of information while EPA makes the decision or as a joint decision-maker. If a stakeholder is to be included at one step in the process, then they should be included throughout. However, the type and level of involvement can and should vary from step to step.

During the process, stakeholders may attempt to increase their share in the process. In such cases, the chairperson must be willing to intervene. Therefore, it is important that the chairperson be regarded by all parties as sufficiently objective (i.e., not directly in the EPA chain-of-command). The regular reevaluation of the mission statement can be a way of dealing with changing roles within the process. Also, the group noted that proper information gathering at the outset will produce better role identification for stakeholders.

Given all of the emphasis placed on stakeholder involvement, it is important to recognize potential problems. Greater stakeholder involvement in the decision-making process does translate into better reception at the end of the process. However, it does mean that stakeholders' expectations also increase, as they feel justified in expecting some return for their contributions to the process. In response, it was suggested that a written document explaining the decision and the issues surrounding each point of view should be developed. This document could serve as a record of the process. In addition, an effort should be made to insure that the public understands the risk tradeoffs involved in the Agency decision-making. EPA should explain at the outset of the process what the risk numbers mean with regard to human health.

With good planning, stakeholder involvement can be very useful in decision-making. It is in EPA's best interest to seek out stakeholders, encourage their involvement, and, when possible, create schedules which increase rather than decrease the likelihood of involvement. If particular stakeholders can be identified, but it is not possible for them to be fully involved in the process, it is worthwhile to identify sub-issues that are important to those stakeholders and work to include them at some level.

The implications for stakeholder involvement are amplified during the analysis step and it is therefore especially important to be creative in reaching out to stakeholders. Industry often has the fewest obstacles to its involvement, due to its general ability to draw upon financial, technical, and personnel resources not usually available to non-profits, the public, or other interest groups. Several ideas were proposed, including the posting of data and information on the web. The guiding principle was to increase the number of people with access to existing data in order to increase the number of analyses considered in the decision-making process.

It is often necessary to level stakeholder influence, so that industry input does not outweigh the input of other groups. Grant money can enable other stakeholders to conduct their

own analyses, although EPA technical assistance grants cannot be used for this purpose. Instead, other groups and industry can be encouraged to provide funds.

Summary

During the plenary session, participants identified the most important aspects of stakeholder communication. First, it is necessary to facilitate their involvement early in the process. An understanding of the initiating event for the action to be undertaken can guide the level of stakeholder involvement. Examples of initiating events include mandates by statute, problems which EPA has the authority to research but not regulate, or the identification of an entirely new issue. The style of involvement can range from simply providing information to consensus-building to joint decision-making. The role of the stakeholders can be different throughout the process. Finally, the decision-making process for each action should be documented to show all aspects that were considered.

3.5 Considerations in using FACA Committees (Deborah Dalton, Jasmine Chapman - OGC)

The Federal Advisory Committee Act (FACA) provides requirements for groups of non-Federal stakeholders that are established by the Federal government for the purpose of providing advice or recommendations to the Federal government. Such groups require many of the same public-involvement activities already recommended for stakeholder groups. They also bring a level of commitment from EPA management and committee members beyond the simple exchange of information to establishing promises and commitments. However, they also require a charter and significant resources. In fact, an Executive Order mandated that FACA committees be reduced by one-third and that spending on each be reduced by five percent. EPA staff can form groups that provide the benefits of a FACA group without incurring the costs.

The EPA Office of General Counsel (OGC) discussed the definition of a FACA committee. A FACA group includes non-government personnel and has a cohesive organizational structure. If that cohesive structure is a result of EPA effort, and the group renders specific advice or recommendations, FACA applies. If the organizational structure of the group is not a result of Agency effort, but the group is subject to strict Agency management and control, FACA applies if the controlled group renders specific advice or recommendations. Groups that are convened by an EPA contractor, whose members are chosen by the contractor, and EPA performs no work related to the group, are not covered under FACA. In general, the groups can move along a continuum, from acting less like a FACA group to more like a FACA group, depending on the means of establishing the group, selecting the group members, directing or controlling the group's work, utilizing the group, and receiving advice from the group.

FACA groups are required to obtain a charter, maintain a balanced membership, hold open meetings, allow the public to speak, announce meetings in the *Federal Register*, keep minutes or summaries, and make committee documents available for public inspection.

Because the margin for interpretation of EPA involvement can be quite fine, it is best to mitigate potential challenges by following the public participation requirements under FACA. The public should be involved in the meetings of the group. Documents related to the group

should be circulated to all attendees during meetings, including any members of the public in attendance. All options suggested should be published, even if not accepted. Group meetings should be held in places which are accessible to the public. Balance is important and all view points should be represented and heard; those who are excluded will be the ones to challenge decisions later.

More information on FACA can be found at the following Internet websites: http:// policyworks.gov/org/main/mc or http://policyworks.gov/FACA_Townhall.

3.6 The Federal Facilities Cleanup Case (Marsha Minter - OSWER)

The Federal Facilities Environmental Restoration and Reuse Dialogue Committee (FFERDC) was a FACA group that convened between 1992 and 1996. It was made up of fifty members of the public and organizational representatives who met to develop consensu-policy recommendations aimed at improving the environmental cleanup and restoration process at Federal facilities. The group was chaired by Administrator Browner and provided a forum to discuss recommendations and build a consensus for solutions. The group provided interim recommendations to improve public information and set priorities based on available resources. The group's final report, entitled *Consensus Principles and Recommendations for Improving Federal Facilities*, included fourteen principles to provide a basis for making Federal facility cleanup decisions, as well as monitoring and facilitating stakeholder involvement associated with cleanup operations. Citizen Advisory Boards are outgrowths of the FFERDC group recommendations.

Principle Number 9 is particularly relevant to risk assessment. It states that "risk to human health and the environment is an important and well-established factor that should continue to be a primary consideration in Federal facility cleanup decision-making, including setting environmental cleanup priorities and milestones." Risk assessments should consider communities of color and low income, particularly susceptible sub-populations, populations exposed to multiple hazards, and workers in particular. While fiscal constraints do not justify failing to take actions to protect human health and the environment, they may result in the need to set priorities about what cleanup actions can occur in any given year.

Many lessons were learned from this FACA group experience. First, it is important to know which stakeholders should be included and to do so from the beginning of the process. In this case, tribes and environmental justice groups were not included when FFERDC first convened. When it was discovered that they should have been involved, some parts of the process had to be repeated. Second, it is important that communication extend beyond public relations-style outreach to two-way communication with all stakeholders. It is important to include stakeholders who will be critical and hear their views. Many methods are available to distribute information beyond the *Federal Register* or the newspaper; different avenues should be used to ensure that all members of the community are reached. Membership in a stakeholder group should mirror the diverse interests within the community. Encouraging various stakeholders to work together creates a partnership, which better identifies common interests and results in better decision-making by EPA.

When groups involving the public are convened, EPA should be prepared to handle the anger of citizens. For example, when the Department of Defense began involving the public in the cleanup of defense sites, complaints which had been festering over time flooded stakeholder meetings, including the loss of jobs from base closures to past contamination which was not disclosed.

It is important to include groups without the resources to participate fully by engaging in activities to build this capacity in the communities. Technical Assistance Grants are one method of doing this through the Superfund program. Research grants and technical outreach services can be used as well. These methods are designed to assist communities in hiring technical advisors to interpret scientific documents, not to conduct their own research.

3.7 Day 2 Wrap-Up

At the end of the second day, workshop participants were again asked to consider key points they would wish to convey to the EPA Administrator. This time, the focus was on facilitating stakeholder communication throughout the risk-management process. Participant statements are given below:

- Early planning for stakeholder involvement is essential. Stakeholders must be identified early in the process and their participation scheduled from the beginning. They should also be notified well in advance of the beginning of the process so that they can prepare both their responses to issues and their own budget and resources. Their involvement should continue throughout the process, even if their roles change.

- Both the stakeholders and the Agency itself must be clear on the role of stakeholders in a given situation; it is important to acknowledge that consensus is not always sought or possible.

- Resources and effort for stakeholder involvement must be committed at the beginning of the process; early efforts will drive success at the end.

- If a stakeholder attempts to circumvent the negotiating process by contacting senior management at EPA, they should be sent back to work through the process rather than given concessions outside of it.

- EPA staff must be given the authority to negotiate and make decisions; when given, those negotiations and decisions must be supported by senior management.

- EPA staff must have access to the training, time, and resources, including qualified, neutral facilitators, necessary for meaningful stakeholder involvement. For example, a facilitation services contract is available through OSWER.

- The Agency must follow through on its commitments. For example, if an evaluation step has been promised during the decision-making promise, the

evaluation must be completed and the results made available to stakeholders in a useable format.

- Both EPA and the stakeholders must recognize that change and compromise are necessary to solve problems. While stakeholder issues will be considered, not all parties will obtain the outcome of their choice.

- Funding for technical assistance should be given to stakeholder groups, such as environmental or citizen groups, when necessary to ensure that their participation is meaningful. Sources of such funds should be listed. (One of the EPA Regions has published a document listing technical assistance grants available for its programs. The EPA Stakeholder Action Plan states that EPA should determine gaps in these grants and establish similar funding mechanisms in programs lacking them.)

- When a decision has been reached, stakeholders should be informed as to how their input was used and their issues considered. The factors that weighed in on the final decision should be identified and explained.

4.0 Wrap-Up Activities

4.1 Summary of Issues and Action Items (Hugh McKinnon - ORD)

As a possible next step, workshop organizers may present the key points identified by participants regarding risk manager – risk assessor and EPA - stakeholder communication issues to the EPA Administrator and to the Science Advisory Board. A potential third workshop may be held in conjunction with the third workshop in the Community Assessment series. Workshop participants were encouraged to continue to network with their colleagues throughout EPA to share lessons learned regarding these issues. In particular, it is important to improve the dissemination of information from Headquarters to the Regions, and to address perceived rifts between the staff and management within EPA. These issues provide potential themes for subsequent workshops.

4.2 Workshop Evaluation

Ten evaluation forms were returned from workshop participants. Copies of the completed evaluation forms are included in this report as Appendix E. Selected responses to each of three questions are summarized below:

What aspects of the meeting did you find most useful?

- The presentation on opportunities for stakeholder involvement, FACA, and phosphides (similar comment made by several participants). The stakeholder discussion on Day 2 seemed to produce the most valuable set of recommendations for addressing the involvement of these parties in the process, especially in the breakout sessions.
- Breakouts provided great information (similar comment made by several participants)
- Most of the discussions were very useful and to the point. The agenda and meeting were well focused and the speakers were good.
- Bringing together people from different parts of the Agency, who ended up providing a lot of useful information to each other, particularly from senior to junior staff (similar comment made by several participants)
- Useful, needed meeting topic
- Active participation and discussion by attendees
- Regional participation, as well as national programs
- Use of actual case studies
- Discussions of risk manager – risk assessor communication

What aspects of the meeting were least useful?

- Would have liked more complete information on forming and implementing stakeholder groups.
- Perspectives on risk assessor – risk manager communication raised no new issues; the session could have been shorter.
- FACA discussion (similar comment made by several participants). However, it is an important topic for those not already familiar with it.
- Most people already seemed to have a good understanding of communication during the planning and scoping phase.
- Breakout sessions were redundant after plenary discussions or presentations.
- Many registered participants did not attend, so attendance was small. Attendance was skewed heavily toward OPP and OSWER, which were well represented, while the Office of Water (OW) was not represented.

Please indicate specific recommendations you might have to strengthen the discussions/ practicum in the future?

- A presentation specifically about OPP's Reregistration Eligibility Decision (RED) stakeholder involvement.
- Follow up with the program and division offices on the issues raised and how the results will be used within EPA programs, including Superfund and water and air programs.
- Develop some internal EPA suggestions to improve risk manager – risk assessor communication.
- Include more case studies.
- Have presentations on enforcement and legal aspects of the stakeholder process.
- Seek broader and greater participation and wider representation across the Agency for presentations and case studies. Continue to encourage the attendance of the Regions so that Headquarters thinking is not isolated and removed from the needs and constraints of those working in the field. Send reminders to registered participants to ensure attendance.
- More detailed advance planning, including definition of the scope and purpose of the meetings, and closer work of organizers with conveners/facilitators/presenters.
- Informal gathering is important; encourage people to plan ahead to share dinner on the evening of the first day.

- Clear explanation of tasks given to breakout groups (this was done better on Day 2).

- Continue with sessions on topics similar to FACA that are important for EPA staff to understand, but which they don't often encounter.

APPENDIX A

List of Participants

Appendix A. List of Participants

Washington, D.C.
July 14-15, 1999

Ed Bender (speaker)
EPA ORD/OSP
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6483
fax 202-565-2925
bender.ed@epa.gov

Ben Blaney
EPA ORD
26 W. Martin Luther King Drive
MD-235
Cincinnati, OH 45268
tel. 513-569-7852
fax 513-569-7680
blaney.ben@epa.gov

Darlene Boerlage
EPA ORD/OSP
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6639
fax 202-565-2916
boerlage.darlene@epa.gov

John Bowser
EPA OPPTS/OPPT/Chemical Control Division
401 M Street SW (7405)
Washington, D.C. 20460
tel. 202-260-1771
fax 202-260-8168
bowser.john@epa.gov

Kathryn Boyle
EPA OPPTS/OPP/SRRD/SRB
401 M Street, SW (7508C)
Washington, D.C. 20460
tel. 703-305-6304
fax 703-308-8005
boyle.kathryn@epa.gov

Amy Caicedo
EPA OPPT/OPP/SRRD/SRB
401 M Street, SW (7508C)
Washington, D.C. 20460
tel. 703-308-9399
fax 703-308-8041
caicedo.amy@epa.gov

Jasmine Chapman (speaker)
EPA OGC
401 M Street, SW (2322)
Washington, D.C. 20460
tel. 202-260-0548
fax 202-260-8392
chapman.jasmine@epa.gov

Deana Crumbling (ad hoc speaker)
EPA Technology Innovation Office
401 M Street, SW (5102G)
Washington, D.C. 20460
tel. 703-603-0643
fax 703-603-9135
crumbling.deana@epa.gov

Barbara Cunningham
EPA OPPT/Office of Program Management and Evaluation
401 M Street, SW (7401)
Washington, D.C. 20460
tel. 202-260-1761
fax 202-2601764
cunningham.barbara@epa.gov

Deborah Dalton (speaker)
EPA OPPE
401 M Street, SW (2136)
Washington, D.C. 20460
tel. 202-260-5495
fax 202-260-5478
dalton.deborah@epa.gov

Kerry Dearfield
EPA OSP/ORD
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6486
fax 202-565-2925
dearfield.kerry@epa.gov

Dennis Deziel (speaker)
EPA OPPTS/OPP
401 M Street, SW (7508C)
Washington, D.C. 20460
deziel.dennis@epa.gov

Jim Goodyear
EPA OPPTS/OPP/Environmental Fate and
Effects Division
401 M Street, SW (7507C)
Washington, D.C. 20460
tel. 703-305-7726
fax 703-305-6309
goodyear.jim@epa.gov

Mark Hartman (speaker)
EPA OPPTS/OPP
401 M Street, SW (7508C)
Washington, D.C. 20460
tel. 703-308-0734
fax 703-308-7042
hartman.mark@epa.gov

Scott Hedges
EPA ORD/NRMRL
401 M Street, SW (8301D)
Washington, D.C. 20460
tel. 202-564-3318
fax 202-565-0075
hedges.scott@epa.gov

Marla Hendriksson
EPA Design for the Environment Program
401 M Street, SW (7406)
Washington, D.C. 20460
tel. 202-260-8301
fax 202-260-0981
hendriksson.marla@epa.gov

Anne Kim
EPA OPPTS/OPPT/Risk Assessment Div.
401 M Street, SW (7403)
Washington, D.C. 20460
tel. 202-260-1273
fax 202-260-1236
kim.anne@epa.gov

Michael McDavit (speaker)
EPA OPPTS/OPP
401 M Street, SW (7508C)
Washington, D.C. 20460
tel. 703-308-0325
fax 703-308-8005
mcdavit.michael@epa.gov

Julia McGinn-Rodriguez
EPA OPPT/Economics Exposure and
Technology Division
401 M Street SW (7406)
Washington D.C. 20460
el. 202-260-1157
fax 202-260-0816
cginn-rodriguez.julia@epa.gov

Hugh McKinnon (speaker)
Associate Director for Health
EPA ORD/NRMRL
26 Martin Luther King Drive (MS-225)
Cincinnati, OH 45268
tel. 513-569-7689
fax 513-569-7549
mckinnon.hugh@epa.gov

Leslie McVickar (speaker)
EPA Region 1
John F. Kennedy Federal Building
One Congress Street
Boston, MA 02203-0001
tel. 617-918-1374
fax 617-565-3660
mcvickar.leslie@epa.gov

Ossi Meyn
EPA OPPTS/RAD/ECAB
401 M Street, SW (7403)
Washington, D.C. 20460
tel. 202-260-1264
fax 202-260-1236
meyn.ossi@epa.gov

Jayne Michaud
EPA OERR/OSWER
401 M Street, SW (5204G)
Washington, D.C. 20460
tel. 703-603-8847
fax 703-603-9104
michaud.jayne@epa.gov

Marsha Minter (speaker)
EPA OSWER
401 M Street, SW (5106)
Washington, D.C. 20460
tel. 202-260-6626
fax 202-260-3527
minter.marsha@epa.gov

Jeff Morris (speaker)
EPA OSP/ORD
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6756
fax 202-565-2926
morris.jeff@epa.gov

C. Bill Murray (speaker)
EPA Region 8
Office of Ecosystems Protection and
Remediation
999 18th Street (8EPR-PS), Ste. 500
Denver, CO 80202-2466
tel. 303-312-6401
fax 303-312-6339
murray.bill@epa.gov

Larry Newsome
EPA OPPTS/OPPT/Risk Assessment Div.
401 M Street, SW (7403)
Washington, D.C. 20460
tel. 202-260-1262
fax 202-260-1236
newsome.larry@epa.gov

Pasky Pascual
EPA ORD
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-2259
fax 202-565-2911
pascual.pasky@epa.gov

Dorothy Patton
Director, EPA OSP/ORD
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6705
fax 202-565-2911patton.dorothy@epa.gov

Heidi Paulsen
EPA OPPTS/OPP/CBEP
401 M Street, SW (7506C)
Washington, D.C. 20460
tel. 703-305-5251
fax 703-308-3259paulsen.heidi@epa.gov

Dan Petersen
EPA ORD/NRMRL/TTSD
26 W. Martin Luther King Drive (G-75)
Cincinnati, OH 45268
tel. 513-569-7831
fax 513-569-7585
petersen.dan@epa.gov

Loan Phan, J.D.
EPA Office of Pesticide Programs
OPPTS/OPP/SRRD/SRB
401 M Street, S.W. (7508C)
Washington, D.C. 20460
tel. 703-308-8008
fax 703-308-8041
phan.loan@epa.gov

Vivian Prunier
EPA OPPT/OPP/FEAD
401 M Street, SW (7506C)
Washington, D.C. 20460
tel. 703-308-9341
fax 703-305-5884
prunier.vivian@epa.gov

Kelly Rimer
EPA OAR/OAQPS
MD-13
Research Triangle Park, NC 27711
tel. 919-541-2962
fax 919-541-0840
rimer.kelly@epa.gov

James Rowe
EPA OSP/ORD
401 M Street, SW (8104R)
Washington, D.C. 20460
tel. 202-564-6488
fax 202-565-2925
rowe.james@epa.gov

Daljit Sawhney
EPA OPPTS
401 M Street, SW (7403)
Washington, D.C. 20460
tel. 202-260-0289
fax 202-260-1216
sawhney.daljit@epa.gov

Karen R. Seeh
EPA Design for the Environment (DfE) Program
401 M Street, SW (7406)
East Tower Room 312
Washington, D.C. 20460
tel. 202-260-1714
fax 202-260-0981
seeh.karen@epa.gov

Victor B. Serveiss
EPA ORD/NCEA
401 M Street, S.W. (8623D)
Washington, D.C. 20460
tel. 202-564-3251
fax 202-565-0078
serveiss.victor@epa.gov

Sarah Smith
EPA OPPT/Economics Exposure and Technology Division
401 M Street SW (7406)
Washington D.C. 20460
tel. 202-260-1547
fax 202-260-0816
mith.sarah@epa.gov

Cindy Stroup
EPA OPPT/Economics Exposure and Technology Division
401 M Street SW (7406)
Washington D.C. 20460
el. 202-260-3889
fax 202-260-0816
troup.cindy@epa.gov

Paula Williams
EPA Region 5, Enforcement and Compliance Assurance Branch, Waste, Pesticides, and Toxics
77 W. Jackson Blvd (DE-9J)
Chicago, IL 60604
tel. 312-353-1243
fax 312-353-4342
williams.paula@epa.gov

Jan Young
EPA OSW/EMRAD
401 M Street, SW (5307W)
Washington, D.C. 20460
tel. 703-308-1568
fax 703-308-0509
young.jan@epa.gov

APPENDIX B

Agenda

Appendix B. Agenda

"Identifying Information Needs for Risk Managers" Workshop Series

Communication and Stakeholder Involvement in the Risk Management Process

July 14-15, 1999
Radisson Barcelo Hotel, Washington, DC

Workshop Objectives

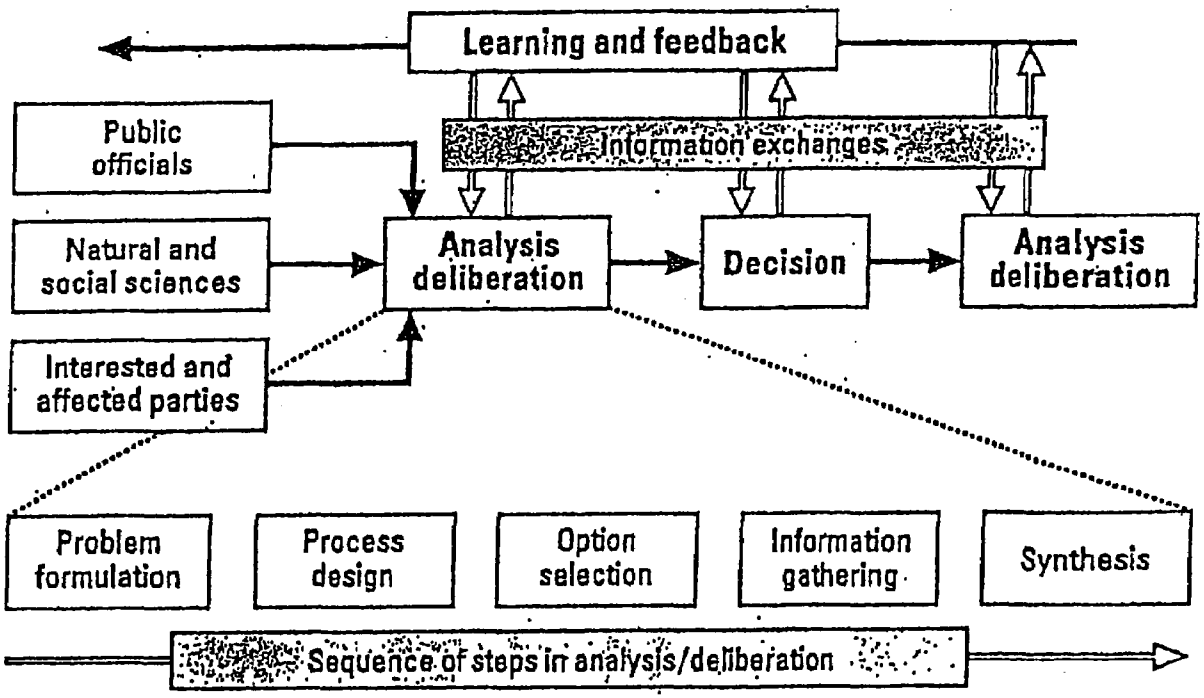
- To discuss risk assessor-risk manager communication, and how this communication does/should inform the decision-making process.
- To discuss stakeholder involvement, and how this involvement does/should inform the decision-making process.
- To identify the extent to which the current models of the risk management process accommodate risk assessor-risk manager communication and stakeholder involvement.

Workshop Chair — Hugh McKinnon, Associate Laboratory Director for Health, National Risk Management Research Laboratory, ORD

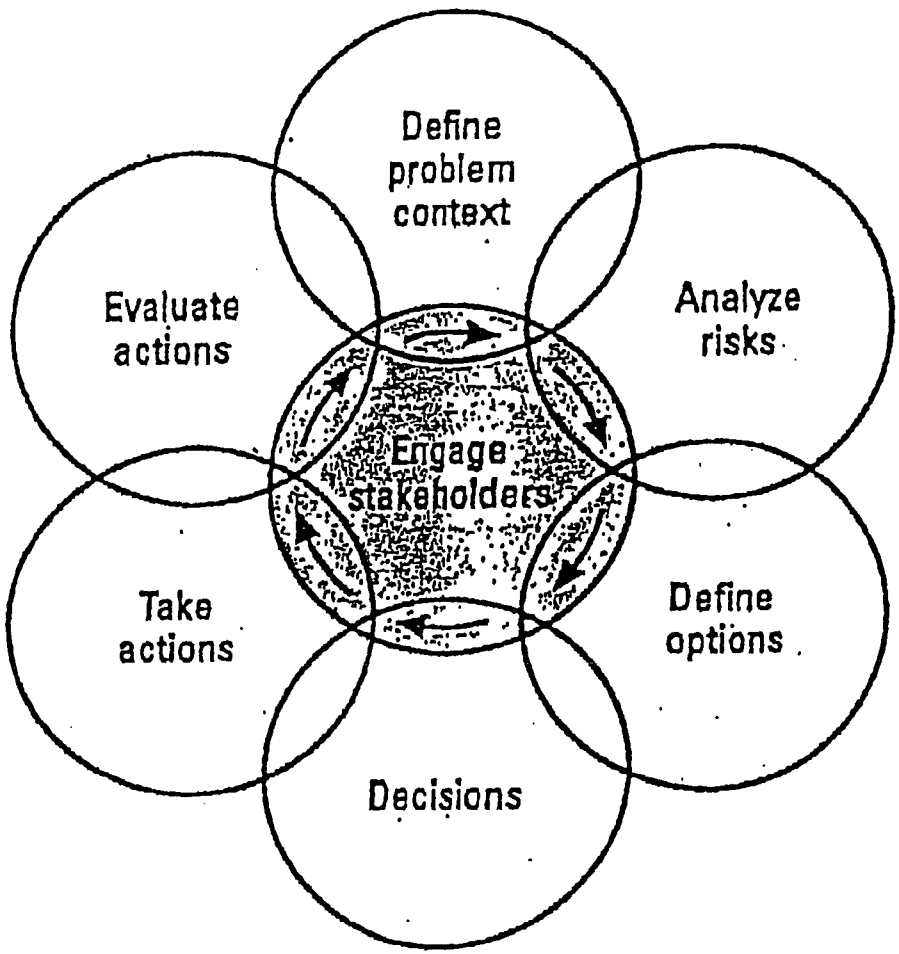
Day 1	Communication Between the Risk Assessor and the Risk Manager	
8:30-9:00	Introduction, brief review of the June workshop	Hugh McKinnon, ORD
9:00-10:00	Plenary Discussion–*Perspectives on Communication between Risk Assessors and Risk Managers*	Hugh McKinnon, ORD
10:00-10:30	Presentation–*Regional Perspective on Risk Assessor-Risk Manager Communication*	Bill Murray, Region 8
10:30-10:45	BREAK	
10:45-11:15	Presentation–*Introduction to Planning and Scoping*	Ed Bender, ORD
11:15-12:30	Case Study Presentations–*Communication Issues*	
	Pownal Tannery Superfund Site	Leslie McVickar, Reg. 1
	Phosphide Fumigants	Mark Hartman, OPP
12:30-1:00	LUNCH	
1:00-1:30	Presentation–*Risk Management Information Models*	Hugh McKinnon, ORD
1:30-2:30	Break-Out Exercise–*Communication during Planning and Scoping*	Jeff Morris, ORD
2:30-2:45	BREAK	
2:45-3:30	Reports from the break-out groups	

Appendix C

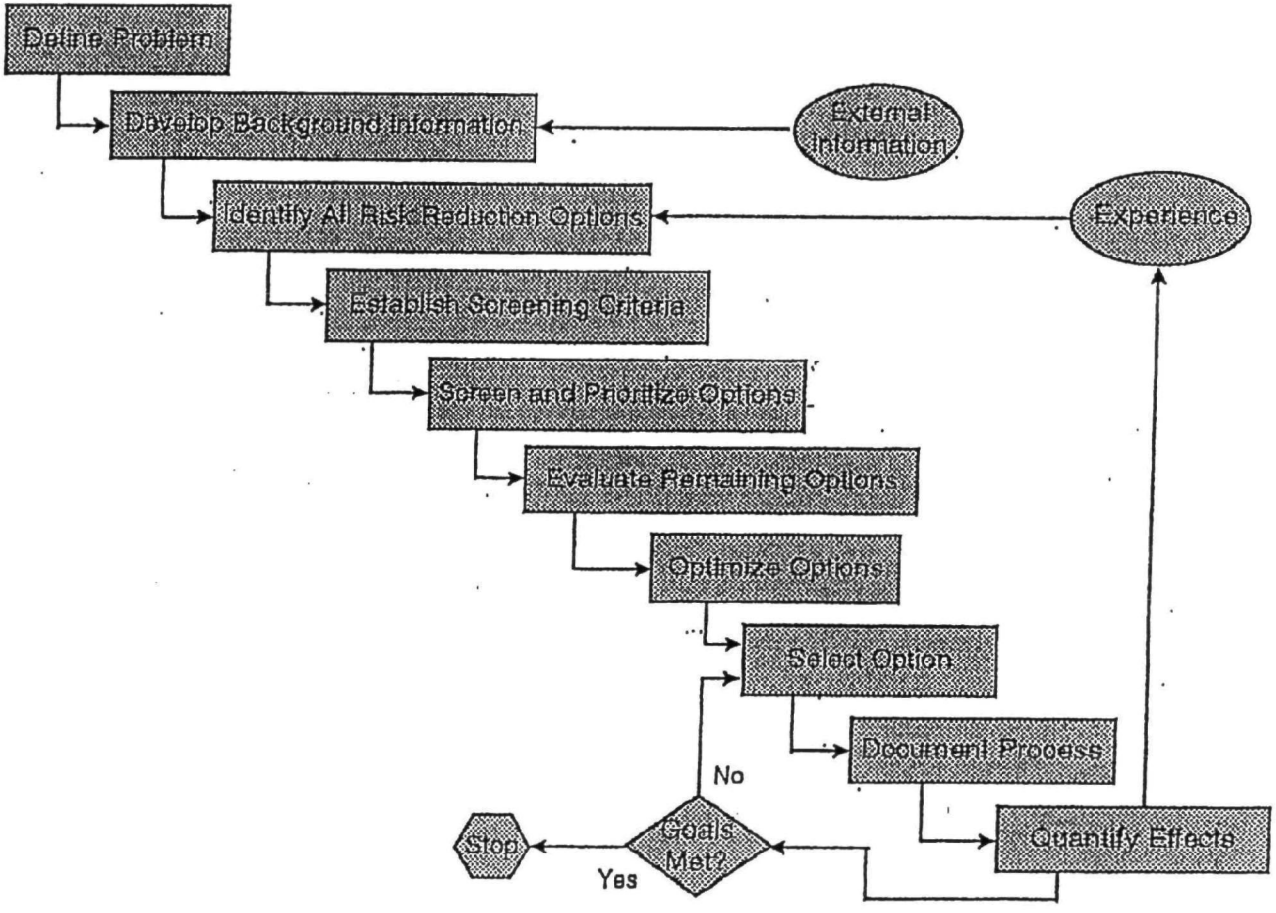
Risk-Management Models



From NRC, 1996 Understanding Risk: Informing Decisions in a Democratic Society

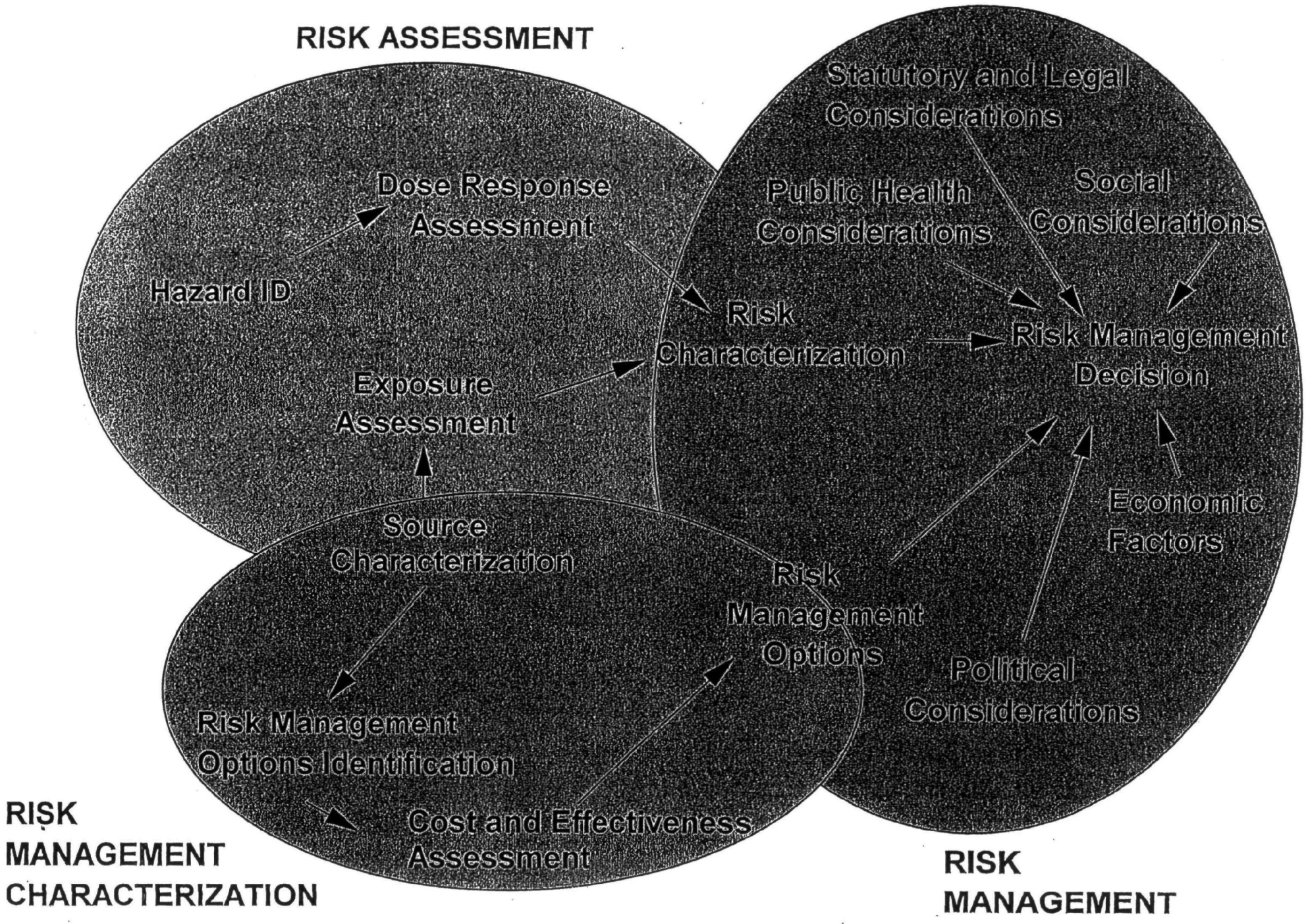


From Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, Framework for Environmental Health Risk Management (Vol.1), and Risk Assessment and Risk Management in Regulatory Decision-Making

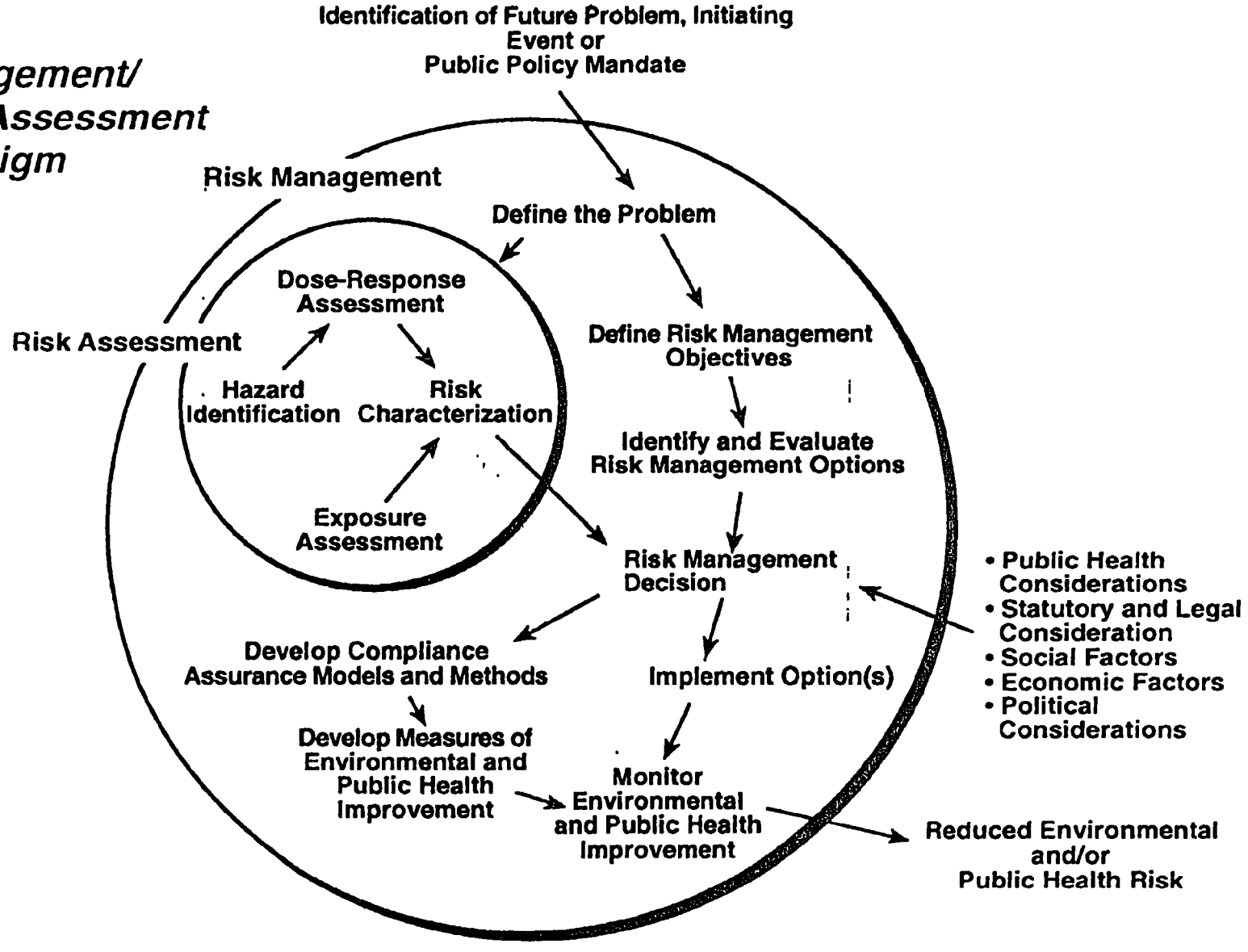


Risk Reduction Option Selection Methodology

From USEPA Science Advisory Board - Integrated Risk Project (Risk Reduction Options Subcommittee)


RISK ASSESSMENT
Dose Response Assessment
Hazard ID
Exposure Assessment
Source Characterization
Risk Characterization
Statutory and Legal Considerations
Public Health Considerations
Social Considerations
Risk Management Decision
Economic Factors
Political Considerations
Risk Management Options
Risk Management Options Identification
Cost and Effectiveness Assessment
RISK MANAGEMENT CHARACTERIZATION
RISK MANAGEMENT

Risk Management/ Risk Assessment Paradigm



Risk Management/Risk Assessment Paradigm

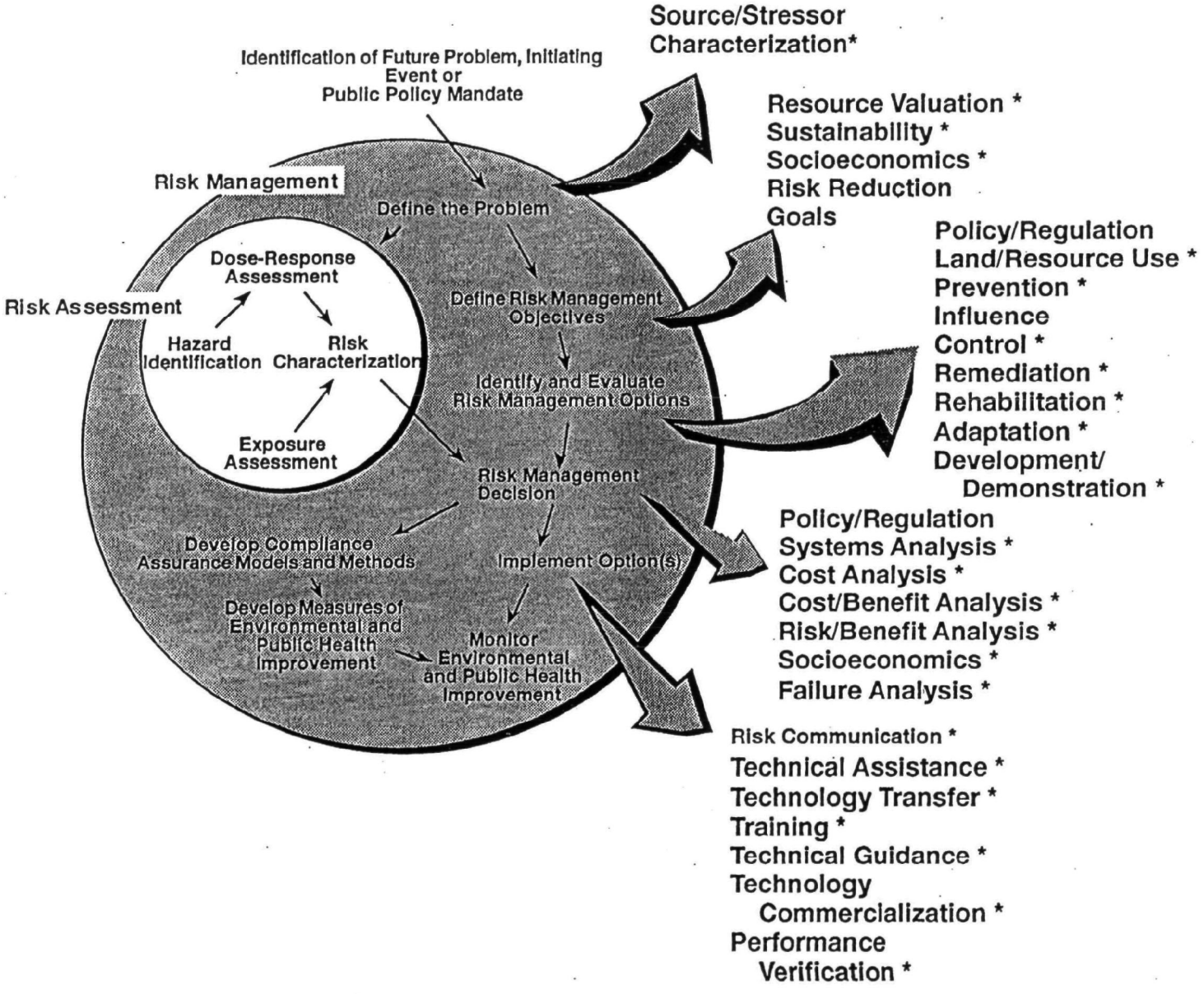


TABLE 1

Comparison of commonalities and differences among frameworks

In spite of differing objectives, ages, nations of origin, and sponsoring agencies, a number of critical themes are common to all frameworks. Tabular entries provide summary descriptions of the stated development purpose and key conceptual innovation of each framework. Agreements among frameworks suggest likely future changes in risk assessment and risk management processes. Differences reveal temporal changes in attitude toward the measurement and management of risk.

Issue	U.S. Risk Commission 1997	Canadian Standards Association 1996	National Research Council 1996	U.K. Department of the Environment 1995	Australia/ New Zealand 1995	U.S. EPA 1992	The Netherlands 1989
Framework's prime objective	Risk management	Environmental decision making	Risk characterization	Risk management	Risk management decision making	Risk analysis	Risk reduction
Assessment versus management	Explicitly management-oriented	Assessment embedded in management	Explicitly management-oriented	Assessment embedded in management	Explicitly management-oriented	Explicitly assessment-oriented	Implicitly management-oriented
Decision making	Decision-oriented, comments on principles and techniques	Decision-oriented, identifies specific decision points	Decision-oriented, decision making used for problem solving	Implicitly decision-oriented, requires balance in decision making	Decision-oriented, stresses a priori criteria for decision making	Not decision-oriented, decisions deferred to risk management	Decision-oriented, includes specific regulatory objectives
Stakeholder input	Strong emphasis on input use	Weak emphasis on input use	Strong emphasis on input use	Implicit emphasis on input use	Strong emphasis on input use	Implicit emphasis on input use	Implicit emphasis on input use
Role of science	Necessary for risk management decision making	Necessary for risk estimation	Necessary for assessment, but insufficient alone	Necessary for risk management decision making	Necessary for risk estimation	Necessary for risk estimation	Necessary for risk estimation
Socioeconomic valuation	Viewed as useful in decision making	Excluded in decision making	Used to broaden risk understanding	Used in decision making due to resource limits	Notes need for cost–benefit analysis	Not included	Costs used to select among regulatory options
Uncertainty analysis	Prefers qualitative to quantitative methods	Requires quantitative methods	Prefers both qualitative and quantitative methods	Stresses qualitative and quantitative methods	Requires qualitative and quantitative methods	Requires quantitative methods	Requires quantitative methods
Risk characterization	Should be both qualitative and quantitative	Emphasizes quantitative approaches	Should be both qualitative and quantitative	Will be partially qualitative due to information gaps	Can be either qualitative and/or quantitative	Emphasizes quantitative approaches	Emphasizes quantitative approaches
Risk prioritization	Important in risk management	Uses qualitative *de minimus* and *de maximus* ranking	Implicit in risk management	Necessary but not always precise	Core management activity completed using criteria	A derivative property of repeated assessment	Completed by comparing risks to standards
Linear versus iterative	Iterative at all stages	Iterative between assessment and management	Iterative at all stages	Iterative at all stages	Iterative at all stages	Iterative between assessment and management	Linear with implicit feedbacks
Key innovation	Includes social, ethical, and economic values in risk analysis	Recognizes the primacy of management over assessment	Recognizes the analytic–deliberative nature of risk-based decision making	Explicit use of the precautionary principle in the face of uncertainty	Emphasizes the comparison of risk to a priori decision criteria	Formalizes the problem identification phase	Specifically states numerical management standards

APPENDIX D

Breakout Group Flip Charts and Posters

Appendix D. Breakout Group Flip Chart Transcriptions

Day 1 Introduction Summary

Perspectives on Internal Communications

Communication

- why it works well
  - continuity
  - trust
  - early risk assessment involvement
- reasons for breakdown
  - workload; getting, holding attention of risk assessors
  - lack of RA training for managers

Why it works:

1.) "What if" scenarios developed by assessors and managers.
2.) Commitment to time frames e.g. statutory deadlines
3.) Extent to which assessor can give interim back-of-the-envelop estimates
4.) Flexibility

Why it doesn't:

Manager's discomfort with RA

Importance of Risk Assessment

- decision making metric - science based
- value of discussion of preliminary findings?
- -"what if" scenario for complex RA, closer to decision point

Assessors' Perspective

- common understanding of expectations
- ideally, information-gathering process is continuous
  - therefore, communication between assessor and manager needs to be ongoing
- legal importance/implication of risk numbers
- in SF, early assessor involvement is important
- breakdown can occur - when risk # used to justify policy
- understanding different perspectives of managers and assessors
- issue of using science to justify predetermined decision
- pressure to not collect data that may reduce uncertainty

Breakout Group 1 Day 1

How to ensure good RM/RA communication to better inform the RM decision making process.

- focus on overlap of RA and RM jobs
- define who is the RA and their qualifications
- ensure that RA is qualified (has expertise)
- ensure that "successors" are well trained/equipped and informed to take over responsibility (pass on institutional knowledge), document, formalize, keep historical record; establish formal process and record consensus and rationale
    - decision tree
    - identify areas of uncertainty
- create a process that works for your group; get consensus to adopt it
- create a work plan
- ensure that info is clear, esp in planning and scoping
    Communication = Clarification
- communication must be reflective of needs and expectations and milestones
- feedback loop built into tasks required and used to evaluate if work was done and if results occur
- debrief after completion (review what worked, etc)
- permanent teams
- clear roles of players, understand perspectives (science, policy, legal, socioeconomic) brought by each player
- keep the team together throughout the process until decision is made
- be up-front and realistic about possible factors that might influence decision and recognize which issues are in assessment and management side
- training for RA and RM together
    - roles and responsibilities
    - key considerations in decision process
    - pragmatic exercises/case studies/ "what if" scenarios
- recognize that communication works on 2 levels
    - internal
    - external (stakeholders)

Breakout Group 2 Day 1

<u>Process</u>

1.) Identify problem/whatever charged to address
2.) Planning & Scoping
    - bounding what you can do
        *legal, statutory, resources, stakeholder concerns
    - explicitly understand what <u>not</u> doing
        *see if others can do other pieces
    - plan how to proceed (conceptual model if can do it)
3.) Analyze factors
4.) Mgt. Options/transaction costs

5.) Evaluate decision

Factors (pieces of the process)

1.) Risk Assessment (health, eco, exposure)
    - planning & scoping
2.) Management goals for waste program
    - mgt. goals for specific case
3.) Cost effectiveness
4.) Technical feasibility
5.) Political feasibility
6.) Community acceptance (stakeholder acceptance includes community, State, etc.)
7.) Legal issues
8.) State acceptance

Risk Assessment:

Who: -risk assessors (depends on driving problem thru the whole process--all the planning and scoping health and eco.)
-Assessors of other factors- risk manager
- Stakeholders

When: - early and often, but depends on level of assessment, number of resources you have, level of trust of organizations' policy

What: - educating risk managers
- Cancer vs. Non-cancer

Breakout Group 3 Day 1

Process with Principles

- Planning and Scoping
    1.) Assemble team and get basic info.; define RM goal - 1st RM and RA have varying goals; ID regs, legal requirements, tech, policy
    2.) Conceptual model - soundly based
    3.) Topics
        - data quality
        - schedule for RA and reviews
    4.) Additional data needs determined and data provided
        - flexibility
        - RA report back to RM as new data available

Analysis - RA
- communication between RM and RA during process
- provide preliminary findings - who needs to review - R|EPA, Fed.parties, stakeholders
- RM dec. - analysis frames options
- RA provides numbers for different scenarios

* If you do a good job planning and scoping, full RA may not be needed

---

Plenary Summary following Day 1 Breakout Groups

Features/Characteristics/Activities Enhancing Risk Assessor/Risk Manager Communication

1.) Team assembles early
2.) Goals set early; conceptual model
3.) Topics
    - assessor/managers/key stakeholders
    - legal requirements
    - time line
    - data quality requirements
4.) Residual data needs to be evaluated/identified early
5.) Continuous communication

Risk Analysis
- data needs
- interim deliverables/preliminary findings
- refine priorities depending upon communication among parties/stakeholders

Risk Management
- defines potential options and evaluates

Day 2 Introduction Summary

STAKEHOLDER INVOLVEMENT

What has worked:

- clarifying what issues are on/off the table
- direct interaction with community = greater understanding
- identify - who, their positions & est. support
- clearly articulate what you want from them
- objectivity
- find the right stakeholders
- ask for alternatives as well as criticisms keep process moving forward
- community interviews (S.F. has formal process)
- recycling S.F. sites initiatives
- follow up- maintaining contact so they know their input has value
- technical assistance grants getting community up to speed on technical issues important to communicate availability

What hasn't:

- politics can short-circuit the process when staff do not have authority to speak for EPA
- posturing

Breakout Group 1 Day 2

- Establish stakeholder participation as priority up-front, but accept unpredictability. (e.g. stakeholder late-comers; politics)

- ID stakeholders & involve early
  - focus on locals
  - develop incentives/tools (e.g. TAG)
  - clarify role early
  - decide when to involve
  - encourage commitment by asking investment of resources
  - educate re: diff. perspectives
- Process
  - focus on problem-solving, not problems
  - focus on process, not outcome
  - acknowledge uncertainties/assumptions
  - follow through to closure
- Handle stakeholder involvement
  - identify all stakeholders
    - * think broadly
    - * outreach/communication
  - involve them early
    - *educate them about each other's position
  - prepare for the worst
    - *can't avoid politics
    - *fully document rationale for the process
  - decide role of stakeholders
    - *individual versus group involvement
  - determine at what points during the process to involve stakeholders
  - be sure involvement is substantive
  - not the usual suspects
  - reduce/avoid gamesmanship
  - focus on local citizens (community advisory panels)
  - look for local continuity
  - encourage resource investment by stakeholders to ensure participation
  - seek other incentives/tools for stakeholder participation
  - seek early agreement/commitment to the process, not to any predetermined outcome
  - accept the fact that the process is unpredictable
  - focus stakeholders on problem solving, not the problem
  - build trust by acknowledging uncertainties/assumptions up-front
  - follow through to closure

Breakout Group 2 Day 2

Planning and Scoping

- Right People (who, how to find, how to motivate)
  * CoC, Bar Assn.
  *technical expertise, previous gov't analysis & contact points
  *announcements, places where people go
  * clinics, churches, libraries, ask parties, networking, meetings, editorial pages
  * establish trust, summaries, technical assistance
- Find out what are issues
- Schedule - level of commitment
  - what is process - motivate
    *issues they care about
    *influence outcome
    *pay ??? - budget, mechanism

Analysis

- FIFRA- DER by FOIA only; Dockets
- Analysis is well documented
- Data available for inspection:
  *Assumptions, Sources, Calculations
  * Readable!
  * Accessible - Web, repository
  * Progress Reports
  * Independent Technical Assistance
  * Layout issues we are analyzing and factors considered
  * Issues in contention

Decisions

- Clarify how much power/influence over decision
- Who is making decision
- Issues of contention- alternative
- Summarize process to date
  * who, what, etc.
  * remind people what it took to get there
- Neutral person run meetings
  *maybe not EPA - establish
- FLEXIBILITY -
  *final or revisit or phase
- Realistic, Implementable

Evaluation & Accountability

- Evaluate effectiveness of dec.
- What are you trying to do!
  - before - at beginning
- Feedback with contact persons
- Build in a revisit testing program
- Track promises
- Technical assistance to stakeholders for monitors
- Data availability - docket, net, repository

Planning and Scoping

Convening Process

1.) Issues
- ask stakeholders
- match issues/goods to resources/time

2.) People
- Who
  *interest
  *expertise
  *balance
- Locate People
  *churches/libraries
  *networks
  *announcements
- motivate
  *issues
  *power
  *resources - tech support, money

3.) Process
- clarify roles
- explain reg: context
- influence over outcome
- ultimate decision maker

4.) Analysis
- clarify issues & factors to be discussed
- document
  *clear
  * readily accessible
  * timely (progress reports)
  *assumptions
  *calculations
  *sources of data
- independent tech experts

5.) Decisions
- review roles/process
- review progress to date
- stay FLEXIBLE
- be realistic
  *clear statement of desired outcome
  *no commitment you can't implement
  *engage stakeholders in implementation/assessment
  *accountability
- neutral person to run meeting

6.) Evaluation
- process begins at decision making phase
  *clear statement of desired outcome

*plan for evaluation
- data to be collected
- who does it
- who is responsible for project

- track all commitments
- tech assistance if needed
- data/analysis readily available (progress reports)

Breakout Group 3 Day 2

Iterate!!!!!!!!!
Same people throughout (base group)
Different types of involvement

- Building stakeholder trust
  - explain level of involvement up front
  - explain how Agency will make decisions up front
  - provide Feedback
    - along the way
    - in evaluation
- How to deal with getting effective involvement from SH groups
- How to deal with hidden agendas
- "Best" approach to SH involvement in analysis phase

Group 3 Summary
- Early facilitator involvement
- Consider the Initiating Event
  - mandate EPA activity
  - new issue
    * process failure or "new" env. problem
  - impacts who stakeholders are and how involved
- Each EPA activity requires diff. stakeholder involvement - design matrix

---

Plenary Summary Following Day 2 Breakout Groups

Planning and Scoping

Facilitation early
Initiating event - Awareness of how it occurred imparts how to involve stakeholders
- mandated
- "build it and they will come" (watershed assessments)
- new issue identified

Information - gathering style
ID appropriate role for stakeholder throughout the process

Summary
- Early involvement of facilitator
- Consider the initiating event
    *mandate
    *new issues (process failure, "new" environmental problem - how do you recognize this IE??)
- Decision Matrix

Appendix E. Hand-Outs

Case Study: Stakeholder Involvement in the Rodenticide Cluster RED

Special Review and Reregistration Division
Office of Pesticide Programs

Background: Rodenticide Cluster RED

Rodenticide Cluster RED indirectly Addresses:

- *Warfarin;*
- *Difethialone;*
- *Vitamin D-3;*

Registrations of *new* rodenticide active ingredients to be used in residential settings...and other places that children may frequent."

Background: Rodenticide Cluster RED

The Agency concluded that rodenticides as currently used pose a significant risk of accidental exposure to humans, particularly children, household pets, and non-target animals.

RED uses data collected by the American Association of Poison Control Centers (AAPCC) for 1995 and 1996

- 1995 data: 17,187 human exposures
  14,900 children <6 exposures

- 1996 data: 17,601 human exposures
  13,362 children <6 exposures

Background: Rodenticide Cluster RED

A two-phased approach was implemented by the Agency to address risk concerns

PHASE 1: Short-Term Risk Mitigation:

- Indicator Dye and Bittering Agent;
- Improved Labeling Requirements;
- Restricted-Use Classification for Tracking Powders;
- Restricted-Use Classification for Field Products;
- Change in % A.I. for Field Uses of Chlorophacinone and Diphacinone;

Background: Rodenticide Cluster RED

PHASE 2: Long-Term Risk Mitigation:

"The Agency will form a stakeholder group and hold a series of meetings to discuss means of significantly reducing exposures to children."

Implementing the Stakeholder Process

First RED to use stakeholder process;

General Guidance: Convene a stakeholder group consisting of members from industry, states, CDC, CPSC, AAPCC, rodent-control experts, members of environmental community, and medical community.

- Convene meetings no later than 90-days from issuance of the RED;

- Conclude process no later than 9-months from issuance of the RED;

Implementing the Stakeholder Process

"Expert Panel" convened: **The Rodenticide Stakeholder Workgroup**

Established as a workgroup to the Pesticide Program Dialogue Committee (PPDC);

27-member workgroup (see attached members list);

- Workgroup Assembled: Aug. 1998 - Feb. 1999

First Meeting: March 30, 1999

The Rodenticide Stakeholder Workgroup

Meeting #1: March 30, 1999
Focus: Introductions, workgroup mission, RED background, problem definition

- Meeting #2: June 9-10, 1999
  Focus: Rodenticide background, continued problem definition, solution discussion begins

- Meeting #3: July 14, 1999
  Focus: Options discussion, continued solution dialogue

The Rodenticide Stakeholder Workgroup

Generative Process - Workgroup continues to define problem and look for appropriate solutions.

Last formal meeting of the Workgroup expected in October 1999;

Rodenticide Cluster RED expected to be amended Fall 1999; implemented beginning in 2000;

Rodenticide Stakeholder Process: Lessons-Learned

Better understanding of the problem and risk
- allows for continued analysis;
- educating and informing the Agency and the public;

Increased transparency.

Better incorporates public values into decision-making.

Rodenticide Stakeholder Process: Lessons-Learned

Resource implications are ENORMOUS.

Difficult to find Workgroup balance.

Stakeholder Challenges

Create atmosphere where creative problem-solving can occur.

- Expectations need to be realistic.
- Need sustained, sincere commitment from senior management.

REVISED 7-9-99

MISSION STATEMENT
FOR THE
RODENTICIDE STAKEHOLDER WORKGROUP

MISSION:

The Rodenticide Stakeholder Workgroup (RSW) will advise the U.S. Environmental Protection Agency, through the Pesticide Program Dialogue Committee (PPDC), regarding potential measures to preclude or reduce the occurrence of unintentional exposures of young children to rodenticides in and around residences.

CONSIDERATIONS:

After considering information on exposure cases involving rodenticides and children (<6 years of age) in the home environment, the RSW will consider potential measures to preclude or reduce their occurrence. For the purposes of this workgroup, the home environment is defined as places in and around residences. The definition excludes all other registered use sites for rodent control chemicals, including crop and livestock protection, golf course, and commercial institutions.

The final recommendation(s) for precluding or minimizing unintentional exposures involving young children shall be mindful of the following factors:

- public health benefits of rodenticides
- avoiding the creation or aggravation of other human health "hazards"
- recognizing the equity of those who bear the cost and regulatory burden
- considering the overall economy and efficacy

RODENTICIDE STAKEHOLDER WORKGROUP MEETING

Sheraton Crystal City Hotel
1800 Jefferson Davis Highway
Arlington, Virginia
March 30, 1999

AGENDA

8:30 AM	Registration	
9:00 AM	Welcome/Opening Remarks	Susan Hazen, Acting Deputy Director Office of Pesticide Programs
9:15 AM	Introduction of Workgroup Members	
10:00 AM	Discussion: Workgroup Process Facilitator & Chair Duties PPDC Charter and FACA Ground Rules	Linda Werrell, Facilitator
10:30 AM	BREAK	
10:45 AM	Presentation: Rodenticides Overview	Dennis Deziel
11:00 AM	Presentation: Children Incident Data	Jerry Blondell
11:30 AM	Discussion: Workgroup Mission Statement	Linda Werrell
12:00 PM	LUNCH	
1:00 PM	Discussion: Exploration of Regulatory Options to Minimize Rodenticide Exposure to Children	Lois Rossi, Chair
2:30 PM	BREAK	
2:45 PM	Discussion: Options (cont.)	Lois Rossi
4:00 PM	Public Comment Period	Linda Werrell
4:30 PM	Defining Next Meeting Agenda	Lois Rossi
5:00 PM	ADJOURNMENT	

Rodenticide Stakeholder Workgroup II

National Rural Electric Cooperative Association Conference Center
4301 Wilson Blvd, Arlington, Virginia – 703-907-5500
(Metro Orange Line, 1 block from Ballston Metro)
June 9-10, 1999
Preliminary Agenda

DAY 1: FRAMING THE ISSUE

JUNE 9, 1999, 9am - 3pm

8:30	Registration	
9:00	Welcome/Opening Remarks	Lois Rossi, Chair
9:15	Rodenticide Benefits: Public Health	Kim Blindauer, CDC Steve Kellner, CSMA
9:45	Rodenticide Benefits: Property Integrity	Bobby Corrigan, RMC Consulting
10:00	RRTF: Rodenticide Use Analysis	Rodenticide Registrants Task Force (RRTF)[1]
10:30	BREAK	
10:45	Anatomy of a Rodenticide Exposure	
	• Comparative Toxicity of Rodenticides	John Redden, EPA
	• Poison Control Center Role	Rose Ann Soloway, AAPCC
	• Emergency Room Perspective	Joseph Wright, M.D.
	• Further Incident Analysis	Jerry Blondell, EPA
12:15	Public Comment Period	Linda Werrell, facilitator
12:30	LUNCH	
1:30	Sub-Group Results: Review of State Incident Data	Bob Wulfhorst, ASPCRO
2:00	RRTF: Incident Data Presented in the Context of the Toxicity, Exposure, and Risk of Rodenticide	Tony Schatz, Reckitt & Colman Rick Kingston, Prosar Internatonal Poison Center
2:30	Public Comment Period	Linda Werrell, facilitator
2:45	Closing Remarks	Lois Rossi
3:00	Offsite Tour - Washington, DC	Mark Greenleaf, DC Department of Health

[1] RRTF represents major manufacturers and formulators of home-use rodenticide products. Companies represented are: Bell Labs, Inc., California Department of Food and Agriculture (CDFA), Consolidated Nutrition, Hacco, Inc., Lipha Tech, PM Resources., Reckitt & Colman, Wilco Distributors, Zeneca Ag Products.

DAY 2: FINDING A SOLUTION

JUNE 10, 1999, 9am - 3pm

8:30	Registration	
9:00	Consumer Labeling Initiative	Amy Breedlove, EPA/OPP, Office of Field and External Affairs Division (FEAD)
9:15	Overview of Pesticide Education and Outreach Programs	
	• Federal Perspective	Claire Gesalman, EPA/OPP/FEAD
	• Federal Perspective	John Impson, USDA,
	• Local Perspective	Mark Greenleaf, Washington DC/DOH
	• State Perspective	Gerry Miller, CDFA
	• Industry Perspective	Bob Rosenberg, NPCA
	• Non-Government Organization Perspective	Lea Johnston, MaryPIRG
10:30	Revisit Workgroup Mission Statement	Linda Werrell
10:45	BREAK	
11:00	Current Risk Mitigation Approaches for Rodenticides	
	• Bittering Agents	Gary Witmer, USDA/APHIS
	• Bait Stations, PR Notice 94-7	Bill Jacobs, EPA
	• Integrated Pest Management (IPM)	John Antonacci, City of Chicago
11:45	Public Comment Period	Linda Werrell, Facilitator
12:00	LUNCH	
1:00	Workgroup Discussion: Rodenticide Use, Toxicity, Incidents, and Options	Lois Rossi
	• Overview of Options Paper	Dennis Deziel, EPA
	• Workgroup Brainstorm: Other Options	Lois Rossi
2:30	Public Comment Period	Linda Werrell
2:45	Setting Agenda for July 14th Meeting/ Closing Remarks	Lois Rossi
3:00	ADJOURNMENT	

Rodenticide Stakeholder Workgroup III
Ramada Inn Plaza Hotel, 901 N. Fairfax St.,
Alexandria, Virginia (Tel 703-683-6000)
July 14, 1999

Agenda

July 14, 1999, 9 am - 4 pm

8:30	Registration	
9:00	Welcome/Opening Remarks	Lois Rossi, Chair
9:15	Discussion: Review Suggested Solutions from June 10 Meeting	Workgroup Members
10:30	Break	
10:45	Discussion: Other Potential Solutions	Dennis Deziel
11:15	Discussion: Preliminary Evaluation of Solutions	Linda Werrell, Facilitator
11:45	Public Comment Period	Linda Werrell
12:00	LUNCH	
1:00	Discussion: Evaluate Potential Solutions • Mission Statement "Considerations" • Implementation Issues and Concerns	Michael McDavit
2:00	Discussion: Monitoring Performance and Results	Linda Werrell
2:30	Discussion: Finalize Recommendation(s)	Linda Werrell
3:00	Break	
3:15	Next Steps	Lois Rossi
3:45	Public Comment Period	Linda Werrell
4:00	ADJOURNMENT	

RODENTICIDE STAKEHOLDER WORKGROUP as of 5/6/99

EPA

Name (alternate)	Stakeholder Category	Affiliation	Address	Phone/fax/E-mail
Lois Rossi, Rodenticide Worgroup Chairperson	Federal Government Pesticide Regulation	USEPA, Office of Pesticide Programs	Director, Special Review & Reregistration Division, (MC 7508C), 401 M Street, SW, Washington, DC 20460	(703)308-8000; 8005 (fax) Rossi.Lois@epamail.epa.gov
Mary Beth Arnett (Barnett Lawrence)	General Public		3619 S. Berryfield Lane, Appleton, Wisconsin 54915	(920) 830-8535; 920-727-7519 (fax) ArnettMB@aol.com
Suzanne Barone	Federal Government Consumer Product Regulation	U.S. Consumer Product Safety Commission, Division of Health Sciences	Room 600 4330 East-West Highway Bethesda, MD 20814	301-504-0477, ext. 1196; -0079 sbarone@cpsc.gov
Jefferson Biakeddy	Tribal Government; Pesticide Regulation	Navajo Nation, Environmental Protection Agency	Pesticide Program, PO Box 339, Window Rock, Arizona 86515	(520) 871-7810; 7818 (fax)
John Antonacci (Terry Howard)	City Gov. - Health & Sanitation	City of Chicago Department of Streets and Sanitation, Bureau of Rodent Control	Bureau of Rodent Control, Room 3-B, 510 N. Teshigo Ct., Chicago, Illinois 60610	(312) 744-6465; 0131 (fax); ss00031@ci.chi.il.us
Robert Corrigan	General Public		5114 Turner Road, Richmond, Indiana 47374	(765) 939-2829 (phone/fax) RCorr22@aol.com
Martha Farkas (Christine Norman)	Canada Government	Pest Management Regulatory Agency, Health Canada	2250 Riverside Dr., Ottawa, Canada, K1A0K9	(613) 736-3772; 3770 (fax) mfarkas@pmra-arla.hc-sc.gc.ca
Mary Ellen Fise	Consumer Group	Consumer Federation of America	1424 16th Street, NW, Suite 604, Washington, DC 20036	(410) 296-4290;4291 (fax); merf@home.com
Ron Grant	Industry - Pesticide Registrant	PM Resources, Inc.	13001 St. Charles Rock Rd., Bridgeton, MO 63044	(314) 394-7489; 9811(fax);
Mark Greenleaf (Alvin Harris)	City Gov. - Health & Sanitation	District of Columbia Department of Health	Department of Health, EHA, Pesticide Programs, 2100 MLK Ave., Washington, DC 20020	(202) 645-6080; 6102 (temp. fax) mgreenle@cyberdude.com (temp)

RODENTICIDE STAKEHOLDER WORKGROUP as of 5/6/99

EPA

Lebelle Hicks	State Gov. - Pesticide Regulation	FIFRA Issues, Research and Evaluation Group (SFIREG)	Maine Dept. of Agriculture; & State, Board of Pesticides Control, 28 State House Station, Augusta, Maine 04333-0028	(207) 287-2731; 7548 (fax); Lebelle.Hicks@state.me.us
John Impson (Shirley Wager-Page)	Federal Gov. - Education	US Dept. of Agriculture - Cooperative State Research, Education and Extension Service	Health, Environmental & Pesticide Safety, Ag Box 2220, 901 D Street, SW (#330), Washington, DC 20250-2220	(202) 401-4201; 6156 (fax); jimpson@reeusda.gov
Bill Jacobs	Federal Gov. - Pesticide Regulation	USEPA - Office of Pesticide Programs	Registration Division, Insecticide and Rodenticide Branch (MC 7505C), 401 M Street, SW Washington, DC 20460	(703) 305-6406; bill.jacobs@epa.gov
Lea Johnston	Environmental Group	Maryland Public Interest Research Group (MaryPIRG)	3121 St. Paul Street, Suite 26, Baltimore, MD 21218	(410) 467-0439; 366-2051 (fax); lea905@aol.com
Steve Kellner	Industry - Pesticide Registrants	Chemical Specialities Manufacturers Association	1913 Eye Street, NW Washington, DC 20006	(202) 872-8110/x3036; 8114 (fax); skellner@csma.org
Edward Marshall (Kelly Rahn)	Industry - Pesticide Registrant	Lipha Tech, Inc.	3600 West Elm Street, Milwaukee, WI 53209	(414) 351-1476; 1847 (fax); edmarshall@liphatech.com
Eileen Moyer (Earle Borman)	Industry - Pesticide Registrant	Reckitt & Colman, Inc.	1800 Valley Raod, Wayne NJ 07474	(973) 686-7387; 7396 (fax); eileen.moyer@reckitt.com
Michael McDavit	Federal Gov. - Pesticide Regulation	USEPA - Office of Pesticide Programs	Special Review & Reregistration Division, Reregistration Branch III (MC 7508C), 401 M Street, SW, Washington, DC 20460	(703) 308-0325; 8005 (fax); michael.mcdavit@epa.gov
Gerald H. Miller (Robert Roberson, Jr.)	State Gov. - Pesticide Registrant	California Dept. of Food and Agriculture	Plant Health and Pest Prevention Services, Integrated Pest Control Branch, 1220 N. Street, Room A-357, Sacramento, CA 95814	(916) 654-0768; 653-2403 (fax) Gmiller@cdfa.ca.gov
Brenda Lee Richardson	Environmental Justice	Women Like Us	3008 24th Place, SE, Washington, DC 20020	(202) 678-1978; 889-1917 (fax);

RODENTICIDE STAKEHOLDER WORKGROUP as of 5/6/99

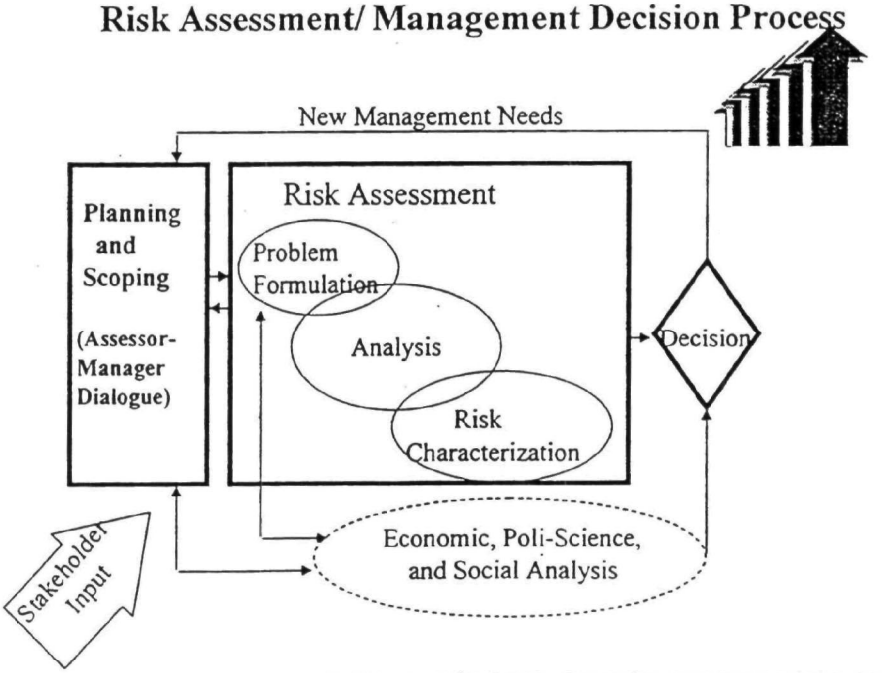
EPA

Bob Rosenberg	Industry - Pesticide Applicator	National Pest Control Association & PPDC	8100 Oak Street, Dunn Loring, VA 22027	(703) 573-8330; 4116 (fax); rrosenberg@pestworld.org
Carol Rubin (Kim Blindauer)	Federal Gov. - Public Health	US Dept. of Health & Human Services - Centers for Disease Control & Prevention	Nat. Center for Env. Health, Health Studies Branch, Mail Stop F-46, 4770 Buford Highway, NE, Atlanta, GA 30341-3724	(770) 488-7350; -7557 (fax) chr1@cdc.gov
Rose Ann G. Soloway	Medical Community	Associate Director, American Association of Poison Control Centers	3201 New Mexico Avenue, NW, Suite 310, Washington, DC 20016	(202) 362-7217; -8377 (fax) ras@poison.org
Cisse Spragins, PhD (Jean Fugate)	Industry - Pesticde Registrant	Agent for Bell Laboratories, Inc./Rockwell Labs.	1117 Marquette Avenue, Suite 2402, Minneapolis, MN 55403	(612) 339-4933; 4943 (fax); cspragins@rockwelllabs.com
Joseph Wright, MD	Medical Community - Emergency Pediatrics	Children's National Medical Center	Dept. of Emergency Medicine, 111 Michigan Avenue, NW, Washington, DC 20010	(202) 884-4177; 3573 (fax); jwright@cnmc.org
Bob Wulfhorst (Carl Falco)	State Gov. - Pesticide Regulation	Association of Structural Pest Control Regulatory Officials (ASPCRO)	Ohio Dept. of Agriculture Pesticide Regulation, 8995 East Main Street, Bldg. 1, Reynoldsburg, OH 43068-3399	(614) 728-6383; 4235 (fax); wulfhorst@odant.agri.state.oh.us

Planning and Scoping for Risk Managers and Assessors

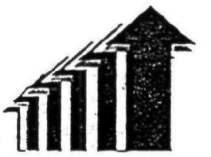
Ed Bender
Science Policy Council Staff
July 14, 1999

Risk Assessment/ Management Decision Process



Cumulative Risk Guidance Planning and Scoping Steps

1. *Discuss why the assessment is needed*
2. *Define the scope of effort*
3. *Determine context (What's in/out?)*
4. *Develop a conceptual model*
5. *Formulate the problem and Analysis Plan for the Assessment*



Problem Formulation Dialog

Risk Assessor

1. Background Knowledge
   a. scale of the risk
   b. critical endpoints
2. Available/appropriate data (where?)
3. CR Matrix
4. Gaps
5. Potential RM options

Risk Manager

1. Why is RA needed?
2. Risk Managem't goals
3. Policy concerns
4. Political concerns
5. Timing/Resources
6. Acceptable Levels of uncertainty?
7. Potential RM options

Stakeholders

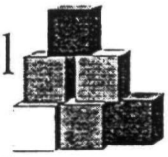
1. Values
2. Impacts

Economists

1. Benefits
2. Tradeoffs
3. RM option costs

Conceptual Model

Dimensions of the Model



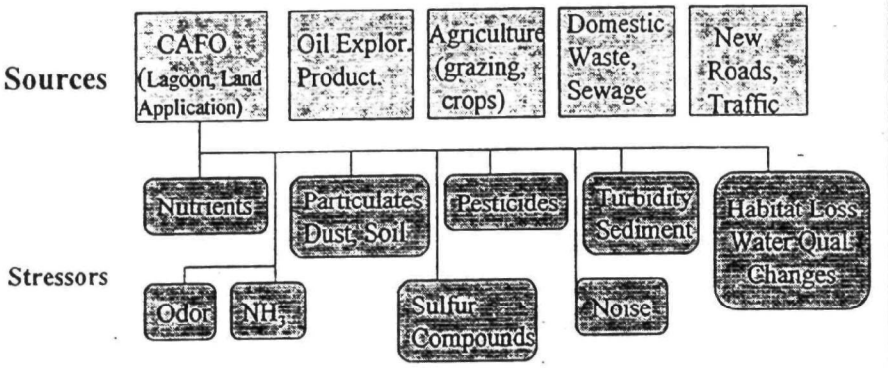
Sources	Stressors	Endpoints
CAFO	Nutrients (N,P,K)	Diseases
Oil &Gas Explor.	Sulfur compounds	Algal blooms
Agriculture (grazing, crops)	Pesticides	Loss of vegetation
	Pesticides	Methemoglobinemia
Domestic Waste	Dust, odor, noise	wetland creation/loss
Road/infrastructure	Ammonia, turbidity	water quality
	Sediment	waterfowl abundance
	Toxic chemicals	Fish/wildlife tox.
		Anxiety, outrage….

Conceptual Models

- Show relationships between assessment endpoints and stressors.
- Reflects both scientific hypothesis and a rationale for accumulating risks from stressors affecting common receptors.

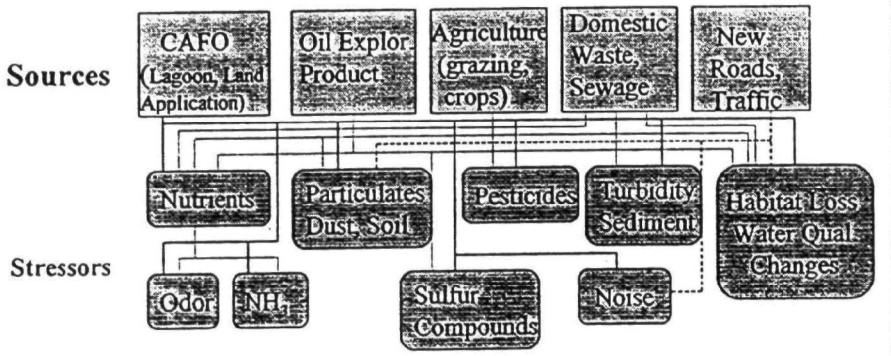
Watershed Preliminary Conceptual Model

(CAFO Stressor Categories)

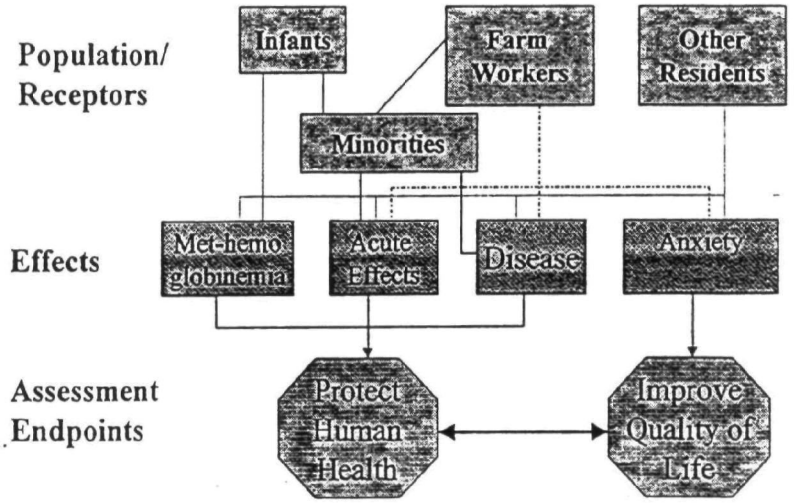


Watershed Preliminary Conceptual Model

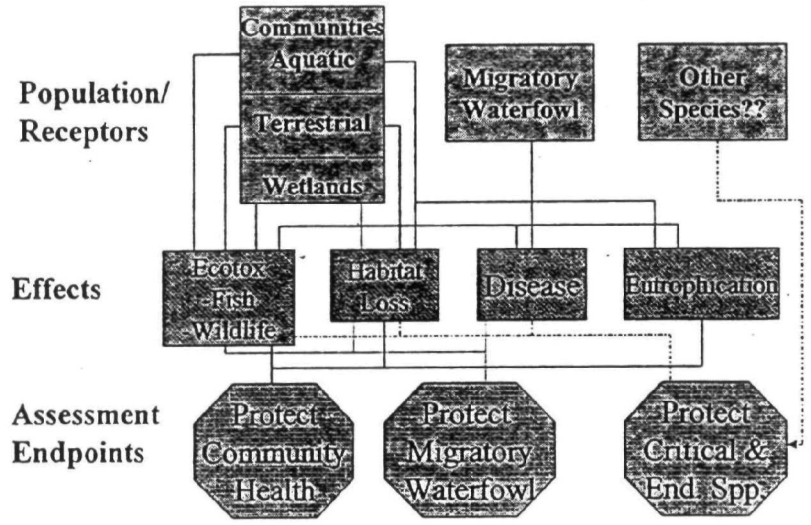
(All Source Contributions)



Human Health Preliminary Conceptual Model



Ecological Preliminary Conceptual Model



Analysis Plan

- Links Planning and Scoping to Assessment
- Identifies critical relationships to evaluate
- Discuss consequences of missing data
- Describe analysis process
- Relate results to risk manager questions
- Discuss recognized uncertainties

Messages from Cumrisk Workshops

- Planning and Scoping and Conceptual Models are important steps, especially for geographically based risk assessments.
- Early discussions with the risk manager are essential.
- More work is needed to reconcile health and ecological risks for cumulative assessments.

Clinch Valley

- Risk Assessors
  - Tetra Tech
  - TVA
- Risk Managers
  - US FWS
  - TNC
  - USDA NRCS
  - farmers

Middle Platte River

Site	5400 sq mi - Nebraska migratory waterfowl
Stressors	hydrologic change, sediments
Effects	wetland loss, channel change
Scientific Approach	landscape ecology approach
Mgt Decisions	water withdrawl, NPS pollution

Middle Platte

- Risk Assessors
  - Queens University
  - Cadmus
  - EPA Region 7
  - EPA ORD NCEA
- Risk Managers
  - EPA Region 7
  - NE Natural Resource Districts
  - Whooping Crane Trust
  - USDA NRCS
  - farmers

Mid-Snake River

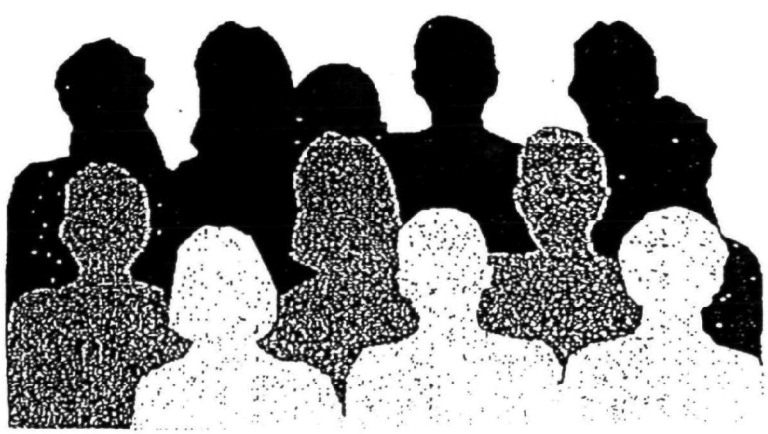
Site	8600 sq mi - Idaho anadromous & cold water fish
Stressors	sediments, hydrologic change
Effects	fish, macrophyte/algal growth
Scientific Approach	sediment sampling study
Mgt Decisions	TMDL regulation, dam licensing

Big Darby Creek

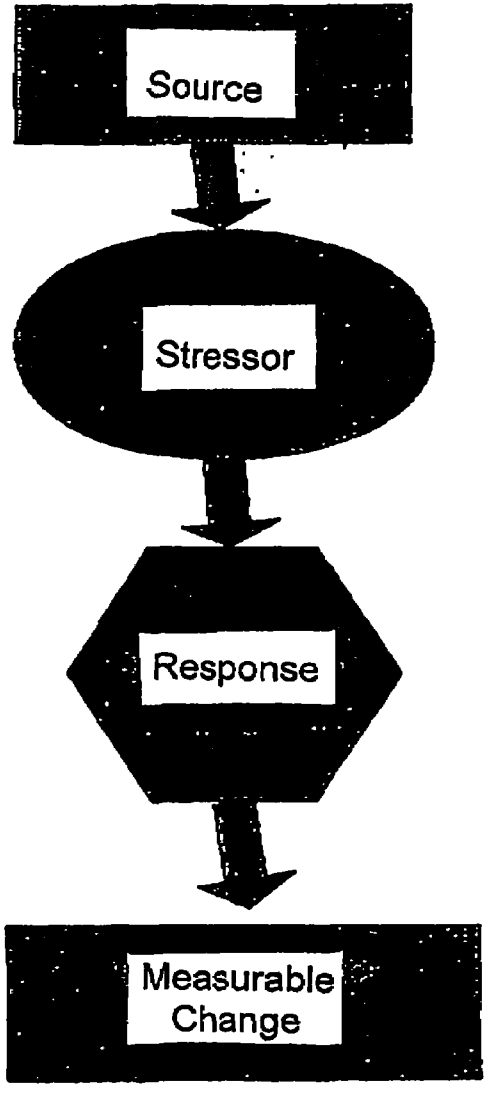
Site	560 sq mi - Ohio water quality, species diversity
Stressors	sediments, nutrients, channel
Effects	fish & macroinvertebrates
Scientific Approach	indices of ecological integrity to evaluate effects
Mgt Decisions	BMPs, future land use

Planning

- Establish a management goal
  - organizational goals
  - laws
  - surveys
  - public meetings
- Agree on focus, scope and complexity



Elements of a Conceptual Model



Conceptual Models
a powerful communication tool

- Illustrate link from human activities to ecological effects
- Help understand multiple stressors, pathways and the watershed approach
- Show different perspectives
- Provide insight and info for decision making

Improvements - Waquoit Bay

- Expand data set, improve model, fund more
- Explaining preliminary findings
- Modified planned presentation

Watershed Eco-Risk Assessment

- Lots of RA-RM Interactions - Teams
  - Management goal for watershed
  - Scope of assessment
  - Understanding the problem and causes
  - Improving the analysis
  - Estimating chnages associated with actions
  - Communicating the findings

THE UNIVERSITY OF TENNESSEE, KNOXVILLE

SADA™

Spatial Analysis and Decision Assistance

Home Page

SADA Main Page
Visualization
Data Exploration
Geospatial Analysis
Risk Assessment
Decision Analysis
Cost Benefit Analysis
Secondary Sampling
Technical Support
Documentation
Coming Soon
Training
Applications
Email Comments
Download Free Version

Spatial Analysis and Decision Assistance (SADA) is free software that incorporates tools from various fields into an environmental assessment problem solving environment. These tools include integrated modules for visualization, geospatial analysis, statistical analysis, human health risk assessment, cost/benefit analysis, sampling design, and decision analysis. The modules in SADA can be used independently or collectively to address site specific concerns when characterizing a contaminated site and when designing remedial action.

SADA was designed to simplify and streamline several of the environmental characterization processes and to integrate the information in order to facilitate decisions about a particular site in a quick and cost effective manner. SADA is applicable for anyone who needs to look at data within a spatial context, such as:

- Statisticians
- Risk Assessors
- GIS Users
- Project Managers
- Stakeholders

SADA output has been very effective in communicating site conditions to non-technical stakeholders as well. Click on any of the topics at left to view more detailed information in each area.

SADA was funded by the DOE and developed by the University of Tennessee in collaboration with Oak Ridge National Laboratory (ORNL).

Main Page| Visualization| Data Exploration| Geospatial | Risk Assessment| Decision | Cost/Benefit| Secondary Sampling| Beta Release| Email Comments | Training| Tech Support

THE UNIVERSITY OF TENNESSEE, KNOXVILLE

SADA™

Spatial Analysis and Decision Assistance

SADA Main Page
Visualization
Data Exploration
Geospatial Analysis
Risk Assessment
Decision Analysis
Cost Benefit Analysis
Secondary Sampling
Technical Support
Documentation
Coming Soon
Training
Applications
Email Comments
Download Free Version

Risk Assessment

SADA provides a full human health risk assessment module and associated databases. The risk models follow the EPA's *Risk Assessment Guidance for Superfund* (RAGS) and can be customized to fit site specific exposure conditions. The following landuse scenarios and exposure pathways are available for both radionuclides and nonradionuclides to calculate risk and data screening levels.

Landuse Scenarios

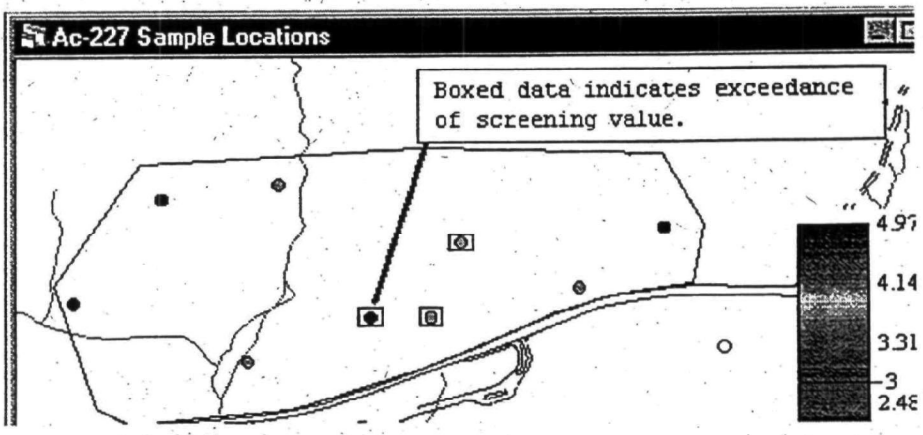
- Residential
- Industrial
- Agricultural
- Recreational
- Excavation

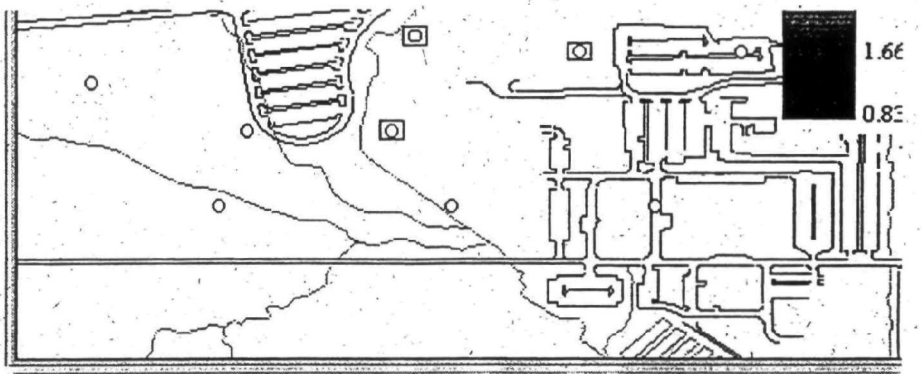
Exposure Pathways

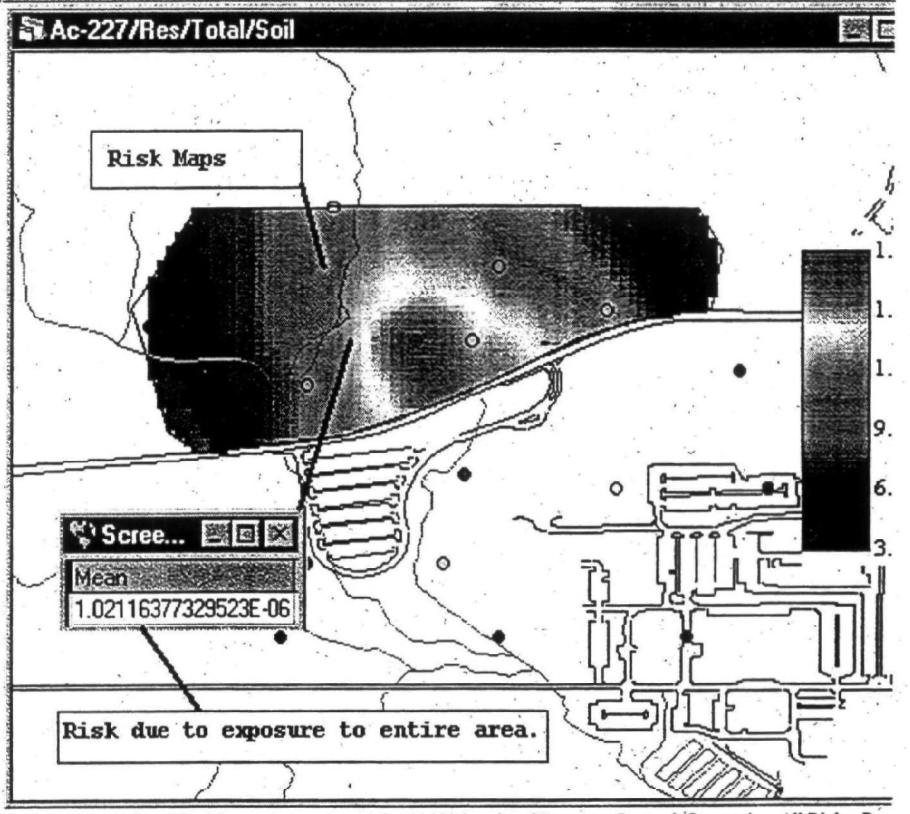
- Ingestion
- Inhalation
- Dermal contact
- External (radionuclides)
- Food consumption
- Combined Exposure

Risk results can be produced in standard tabular format or graphically.

Graphical Results







Main Page| Visualization| Data Exploration| Geospatial | Risk Assessment| Decision | Cost/Benefit| Secondary Sampling| Release| Email Comments | Training| Tech Support

Phosphine Case Study

Communications Issues

OPP Process

- Risk Manager
  - Development of Mitigation Measures
  - Regulatory Products
  - Interactions w/ External Entities
- Team Concept
  - RM leads the team
  - RAs lead assessment teams
  - Communication is Key

Key Aspects of Communication

- Coordination of Interdependent Efforts

  Ex.) Drinking water exposure; %CT

- Fulfillment of Information Needs

  Ex.) Data requirements; Media interactions

- Maintaining Schedules

Key Aspects of Communication

- Setting Priorities
- Informing Management
- Enhance Understanding of Risks
- Development of Mitigation Strategies

When to Communicate??

- In short: Always
- Team Kickoff Meeting
- Development of Assessments
- Development of Mitigation Strategies
- Regulatory Decisions

Phosphine Case: Phase 1 "Uh Oh"

- Out w/ the old in w/ the new
- Got to get it out!
- Industry needs a clue!
- A novel approach
- A journey instead of a trip

Phase 2: Making It Work

- Working together to flatten the learning curve
- Pulling together many minds to strategize
- Educating the industry
- A successful path forward

"The Price Not Paid"

- Failure to meet milestones
- Rework and more rework
- Misinformed, unhappy management :(
- Incomplete assessments
- Poor decisions

RA<->RM Communication

- The key to success is:
  - open
  - honest
  - consistent
  - two-way

COMMUNICATION

Case Study: *Pownal Tannery Superfund Site*

Issue

In 1998 EPA listed the Pownal Tannery in North Pownal, Vermont, as a Superfund site. While a human health risk screening, done for the site in support of an ongoing non-time critical removal action (NTCRA), did not exceed the level of concern typically used to place a site on Superfund's National Priorities List (NPL), other (non-risk assessment) information weighed heavily in the decision to perform the NTCRA and list the site.

Site Description

The Pownal Tannery site is located between Route 346 and the Hoosic River in the Village of North Pownal, in Bennington County, Vermont. The site was a former hide tanning and finishing facility owned by the Pownal Tanning Company, Inc. It has been inactive since 1988 when the company declared bankruptcy. The site consists of three contamination sources: the tannery building complex, a lagoon system, and the tannery's sludge landfill. In total, the Pownal Tannery site encompasses approximately 28 acres.

From approximately 1937 until 1962, untreated tanning process wastewater was directly discharged into the Hoosic River. A lagoon system comprising six lagoons, was constructed in several stages between 1962 and 1971 to receive the tannery's wastewater. In 1982, a state-permitted, lined landfill was constructed on site to receive sludge dredged from a portion of the lagoons. The tannery landfill is situated on a parcel of land across from the Hoosic River and southeast of the tannery building complex. In 1987, two-thirds of the landfill was covered and closed The remaining portion remains uncovered.

The area is a rural and residential community with approximately 3,500 residents Many residents live in rented trailers. The nearest residences are approximately 200 feet from the site and rely upon groundwater from private wells for their water supply. While some site related contaminants have been detected in residential wells in the past, current sampling data indicates that safe drinking water standards are not being exceeded.

Threats and Contaminants

- The groundwater, soil, lagoon/landfill sludge, and building materials are contaminated primarily with metals, semi-VOCs, and dioxin

- Metals, semi-VOCs, and dioxin have been found in site soil/sludge and on building materials at levels that pose an unacceptable direct contact threat.

- Surface water and sediments associated with the Hoosic River are contaminated with several metals, with some exceeding federal benchmark criteria indicating a potential adverse impact to aquatic organisms.

- Access to the site is largely unrestricted.

- While sampling data indicate that the site has not adversely affected the nearest residential wells, continued migration of contaminated groundwater could present a future human health threat.

;sessment

EPA completed a human health risk screening of the site in 1998. Using very conservative assumptions, the assessment indicated low ($< 1 \times 10^{-4}$) risks to the most at-risk groups (adolescent trespassers returning daily to the site, future adult employee). See Separate attachment.

EPA did not conducted an ecological assessment of the site.

Potential risks due to building/landfill condition and location of site to the river (see attached map).

leanup Approach

— The site is being addressed in two stages: initial actions and a long-term remedial phase ·hich will address contamination at the entire site. Following an initial EPA site evaluation in 93, a time-critical removal action was taken in 1993 and 1994 to remove 13,000 pounds of contaminated material left behind in drums and tanks within the tannery buildings. Additionally, e access restrictions were put in place but were subsequently compromised by trespassers is action mitigated the immediate threats to the community.

Between 1995 and 1998, EPA completed an additional preliminary investigation of the urce areas at the site, which included the collection of samples at the lagoons, the landfill and tannery building. In December of 1998, EPA released a proposed plan to the public to address ntamination at the buildings and the landfill. This proposal includes decontamination and molition of tannery buildings, removal of contaminated soil/sludge under tannery buildings to the on-site landfill, capping the landfill and repairing the leachate collection system at the ndfill. A final Action Memorandum, documenting this decision was released in March 1999 d the cleanup has begun and will continue for approximately one year. Contamination of the roundwater, lagoons, surface water, and sediment of the Hoosic river will be addressed during upcoming Remedial Investigation and Feasibility Study (RI/FS), which is also scheduled to gin in the spring of 1999 Through both of these upcoming actions, site access restrictions will addressed.

nvironmental Progress

The initial actions to remove liquid and bulk hazardous materials remaining in the tannery ildings reduced the potential for accidental exposure to hazardous wastes at the site. The upcoming non-time critical removal measures to completely address building contamination and close the landfill will address potential exposures to two of the three source areas at the former nnery.

POWNAL TANNERY
HUMAN HEALTH RISK SCREENING

PURPOSE

To determine whether the contaminants identified at the site pose a current and/or future potential risk to people in the absence of a cleanup, and if an action needs to be taken to protect the public.

LAND USE ASSUMPTIONS

Current: Tannery activities closed. Site is known to be utilized by local trespassers.

Future: Continued trespassing and resumed industrial activities.

CONTAMINANTS OF CONCERN

16 Semi-Volatile Organic Compounds (SVOCs), dioxin, and metals.

EXPOSURES

Current: **Adolescent trespasser** to contaminated building surfaces and soil/sludge in building basements via ingestion and dermal cont[illegible] (direct contact).

Future: Same as current exposure with the addition of exposure to a **future adult employee** at the building through ingestion and dermal contact.

RISKS

There is an **unacceptable current and future cancer risk to adolescent trespassers** that may come into direct contact with contaminants on building surfaces and to soil and sludge under the building.

There is an **unacceptable future cancer risk to an adult future employee** that may come into direct contact with contaminants on building surfaces and to soil and sludge under the building.

Summary of Primary Contaminants of Concern, Maximum Concentrations Detected

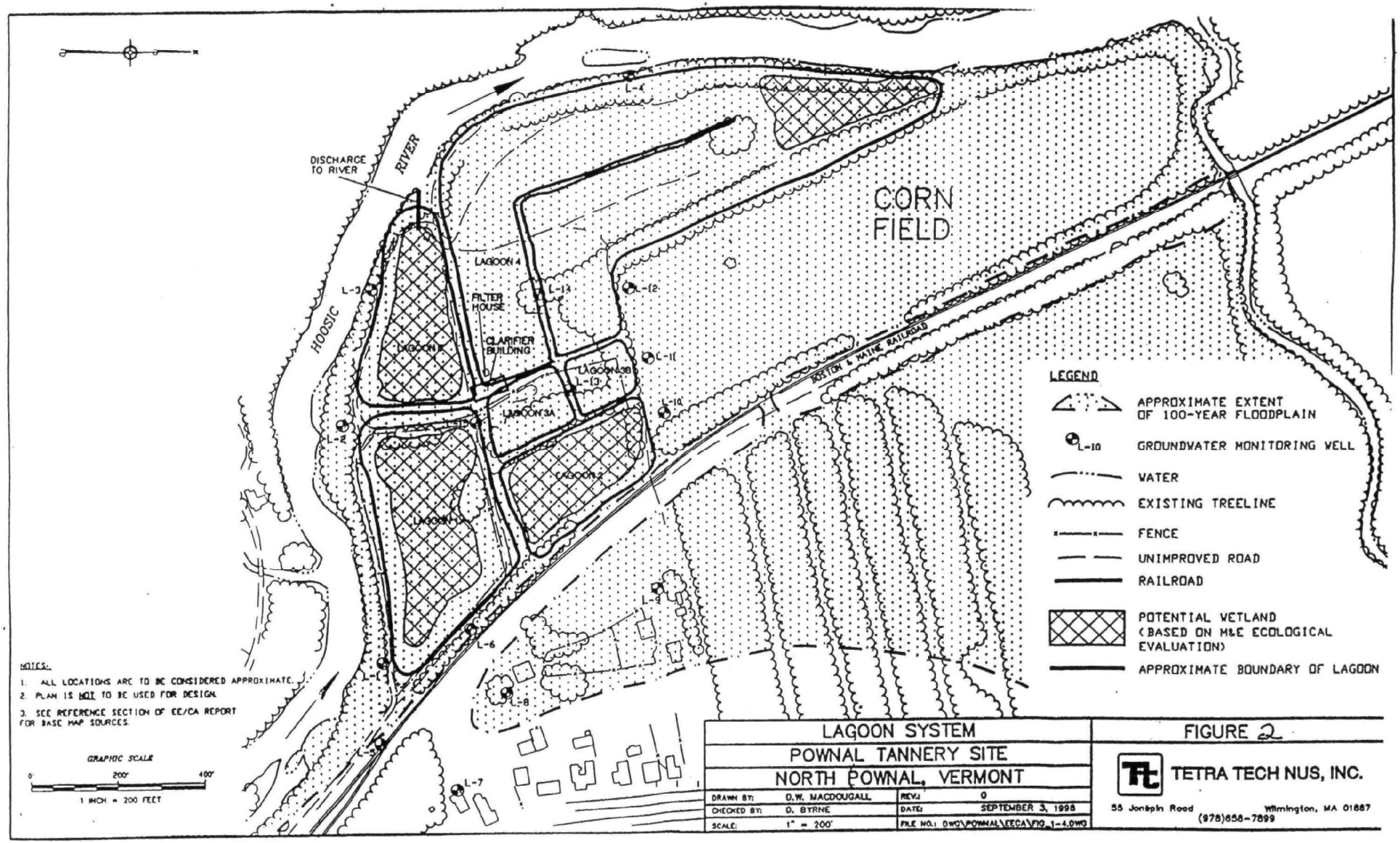
Tannery Building Complex

Soils/Sludge

arsenic (mg/kg)	**63**	parts per million
antimony (mg/kg)	**232**	
barium (mg/kg)	**8,270**	
cadmium (mg/kg)	**33**	
chromium (mg/kg)	**126,000**	
lead (mg/kg)	**1,380**	
manganese (mg/kg)	**2,140**	
nickel (mg/kg)	**606**	
vanadium (mg/kg)	**1,640**	
benzo(a)anthracene (ug/kg)	**56,000**	parts per billion
benzo(a)pyrene (ug/kg)	**63,000**	
benzo(b)fluoranthene (ug/kg)	**74,000**	
benzo(k)fluoranthene (ug/kg)	**45,000**	
indeno(1,2,3-cd)pyrene (ug/kg)	**22,000**	
pentachlorophenol (ug/kg)	**33,000**	
dioxin (ng/kg)	**459**	parts per trillion

Landfill

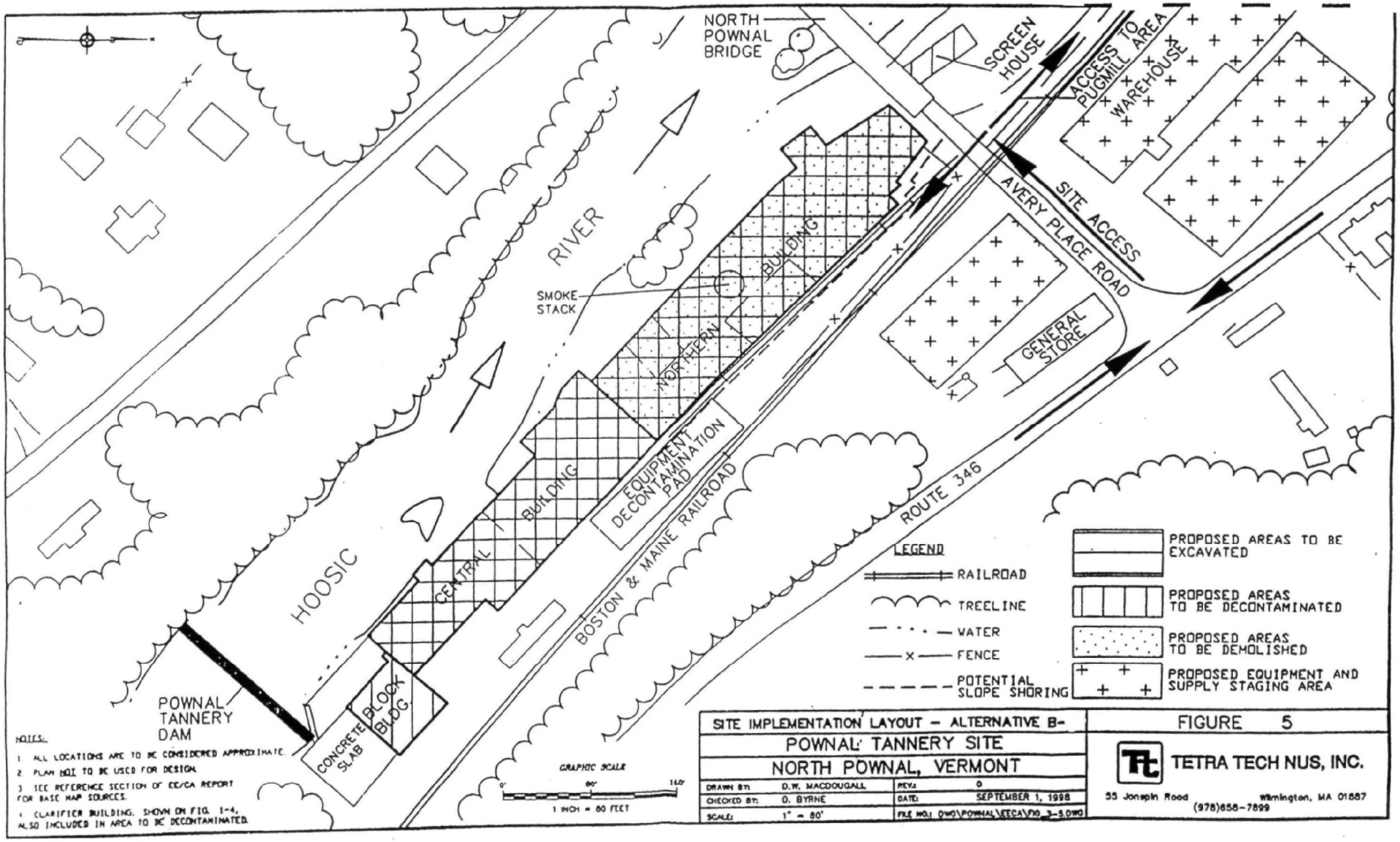
	sludge	Runoff Sediments	
arsenic (mg/kg)	**10**	**9**	parts pe
cadmium (mg/kg)	**76**	NA	
chromium (mg/kg)	**18,900**	**60**	
lead (mg/kg)	**975**	**22**	
manganese (mg/kg)	**3,640**	**3,110**	
mercury (mg/kg)	**39**	**.11**	
zinc (mg/kg)	**171**	**620**	
pentachlorophenol (mg/kg)	**100**	NS	
2,4,5-trichlorophenol "	**51**	NS	
4-methylphenol (mg/kg)	**500**	NS	
phenol (mg/kg)	**200**	NS	
2-butanone (ug/kg)	**740**	NS	parts per billion
dioxin (ug/kg)	**7**	NA	

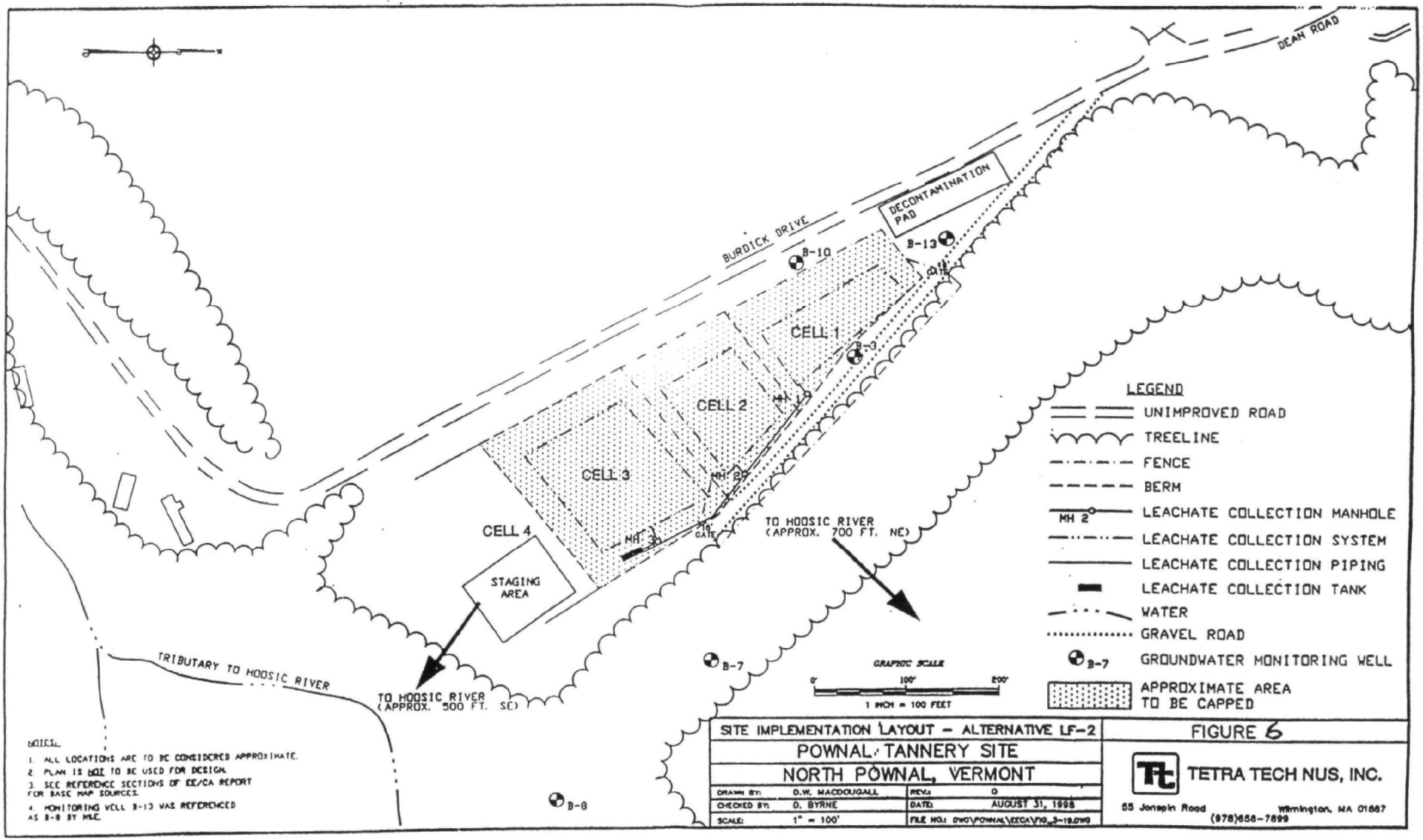


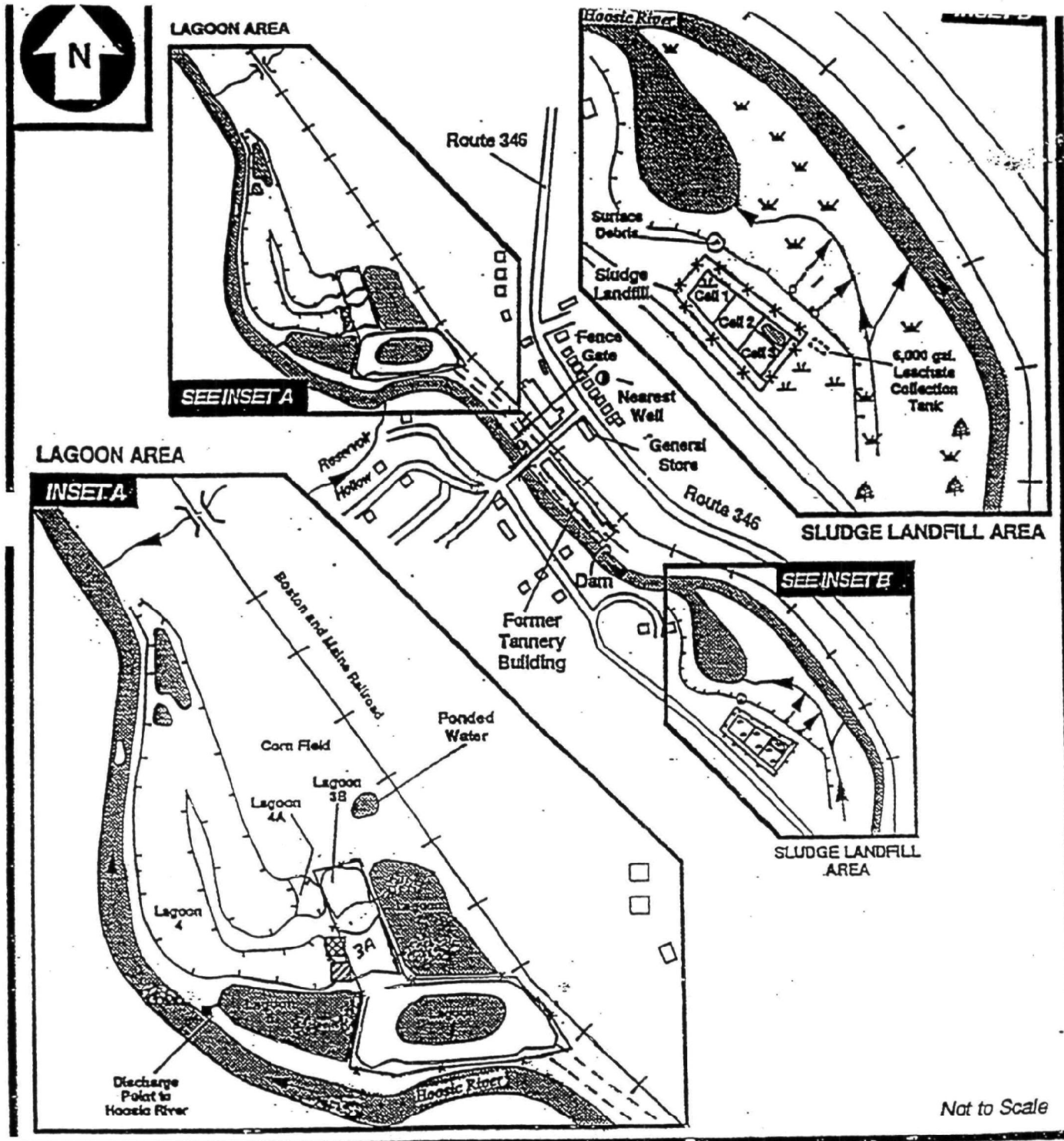
LAGOON SYSTEM			
POWNAL TANNERY SITE			
NORTH POWNAL, VERMONT			
DRAWN BY:	D.W. MACDOUGALL	REV.:	0
CHECKED BY:	D. BYRNE	DATE:	SEPTEMBER 3, 1998
SCALE:	1" = 200'	FILE NO.:	DWG\POWNAL\EECA\FIG_1-4.DWG

FIGURE 2

TETRA TECH NUS, INC.
55 Jonspin Road Wilmington, MA 01887
(978)658-7899


NORTH POWNAL BRIDGE
SCREEN HOUSE
ACCESS TO PUGMILL AREA
WAREHOUSE
AVERY PLACE ROAD
SITE ACCESS
RIVER
SMOKE STACK
BUILDING
NORTHERN
GENERAL STORE
EQUIPMENT DECONTAMINATION PAD
CENTRAL
BUILDING
HOOSIC
BOSTON & MAINE RAILROAD
ROUTE 346
POWNAL TANNERY DAM
CONCRETE SLAB
BLOCK BLDG.
GRAPHIC SCALE
0'
80'
160'
1 INCH = 80 FEET
LEGEND
RAILROAD
TREELINE
WATER
FENCE
POTENTIAL SLOPE SHORING
PROPOSED AREAS TO BE EXCAVATED
PROPOSED AREAS TO BE DECONTAMINATED
PROPOSED AREAS TO BE DEMOLISHED
PROPOSED EQUIPMENT AND SUPPLY STAGING AREA
NOTES:
1. ALL LOCATIONS ARE TO BE CONSIDERED APPROXIMATE.
2. PLAN NOT TO BE USED FOR DESIGN.
3. SEE REFERENCE SECTION OF EE/CA REPORT FOR BASE MAP SOURCES.
4. CLARIFIER BUILDING, SHOWN ON FIG. 1-4, ALSO INCLUDED IN AREA TO BE DECONTAMINATED.
SITE IMPLEMENTATION LAYOUT - ALTERNATIVE B-
POWNAL TANNERY SITE
NORTH POWNAL, VERMONT
DRAWN BY: D.W. MACDOUGALL
CHECKED BY: D. BYRNE
SCALE: 1" = 80'
REV.: 0
DATE: SEPTEMBER 1, 1998
FILE NO.: DWG\POWNAL\EECA\FIG_5-5.DWG
FIGURE 5
TETRA TECH NUS, INC.
55 Jonspin Road
Wilmington, MA 01887
(978)658-7899


DEAN ROAD
BURDICK DRIVE
DECONTAMINATION PAD
B-10
B-13
B-9
CELL 1
CELL 2
CELL 3
CELL 4
MH 1
MH 2
MH 3
10' GATE
STAGING AREA
TO HOOSIC RIVER (APPROX. 700 FT. NE)
TRIBUTARY TO HOOSIC RIVER
TO HOOSIC RIVER (APPROX. 500 FT. SE)
B-7
B-8
GRAPHIC SCALE
0' 100' 200'
1 INCH = 100 FEET
LEGEND
UNIMPROVED ROAD
TREELINE
FENCE
BERM
MH 2 LEACHATE COLLECTION MANHOLE
LEACHATE COLLECTION SYSTEM
LEACHATE COLLECTION PIPING
LEACHATE COLLECTION TANK
WATER
GRAVEL ROAD
B-7 GROUNDWATER MONITORING WELL
APPROXIMATE AREA TO BE CAPPED
NOTES:
1. ALL LOCATIONS ARE TO BE CONSIDERED APPROXIMATE.
2. PLAN IS NOT TO BE USED FOR DESIGN.
3. SEE REFERENCE SECTIONS OF EE/CA REPORT FOR BASE MAP SOURCES.
4. MONITORING WELL B-13 WAS REFERENCED AS B-8 BY MLE.
SITE IMPLEMENTATION LAYOUT - ALTERNATIVE LF-2
POWNAL TANNERY SITE
NORTH POWNAL, VERMONT
DRAWN BY: D.W. MACDOUGALL
CHECKED BY: D. BYRNE
SCALE: 1" = 100'
REV.: 0
DATE: AUGUST 31, 1998
FILE NO.: DWG\POWNAL\EECA\V10_3-18.DWG
FIGURE 6
TETRA TECH NUS, INC.
55 Jonspin Road Wilmington, MA 01887
(978)658-7899



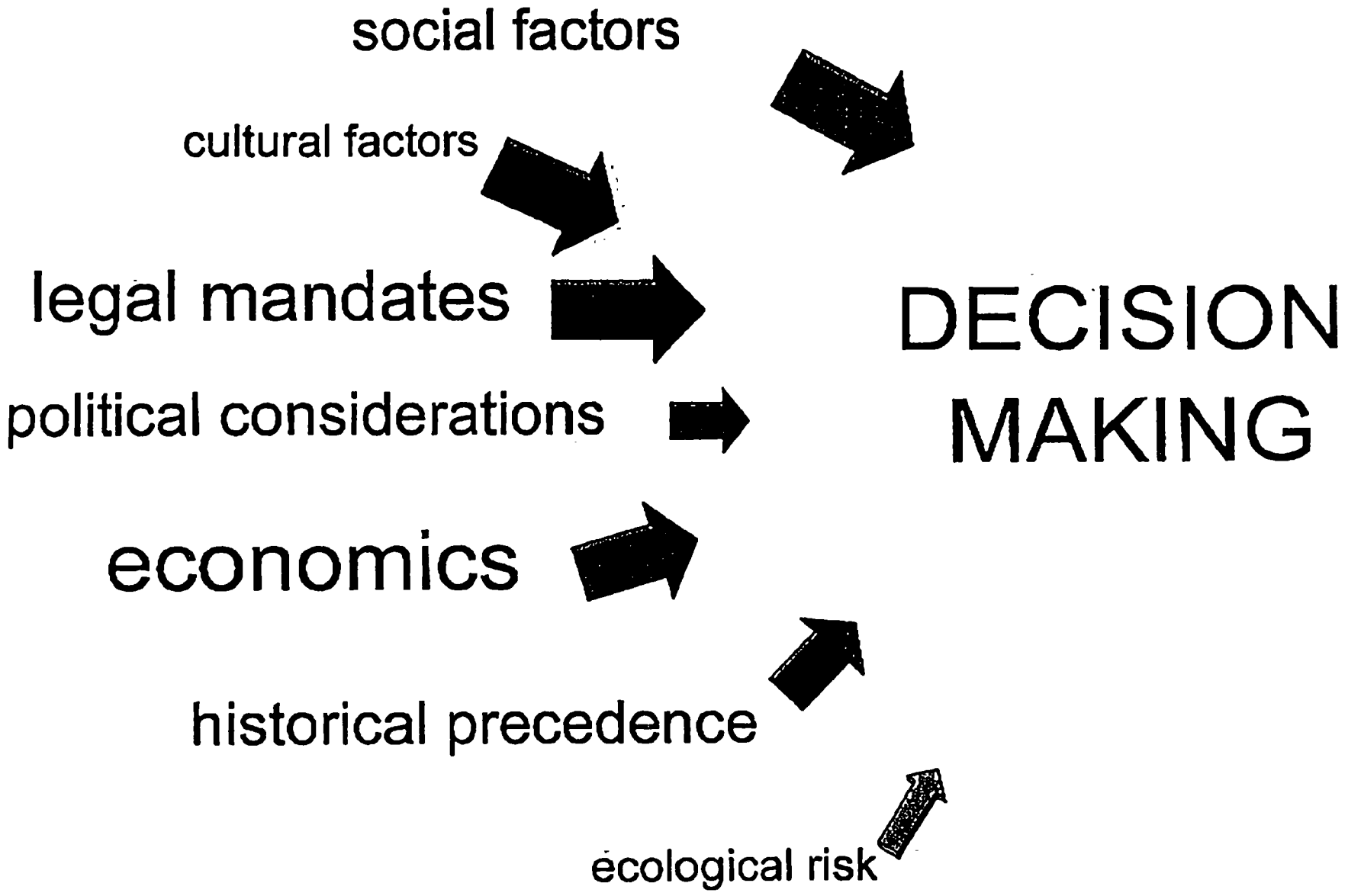
SITE SKETCH

POWNAL TANNERY
POWNAL, VERMONT

Figure 1

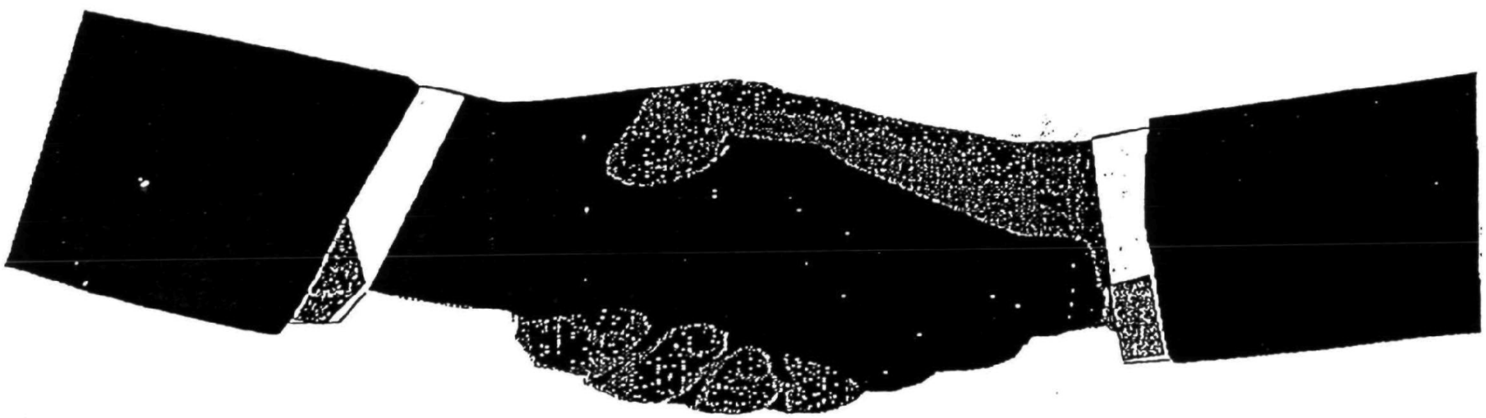
Merging Science with Policy thru 5 Watershed Assessments

- Environmental Science (risk assessors)
- Public Policy (risk managers)


social factors
cultural factors
legal mandates
political considerations
economics
historical precedence
ecological risk
DECISION MAKING

Merging

- Watershed approach
- Ecological risk assessment



Applying the Ecological Risk Assessment Approach

- Ecological risk assessment framework
- Apply principles to real world problems
- Five demonstration sites were selected

Watershed Assessments

Waquoit Bay

Site	20 sq mi estuary - MA scenic, recreation, fishing
Stressors	nitrogen & toxins
Effects	algal growth -> SAV -> fish
Scientific Approach	N loading model & ecological effects model
Mgt Decisions	septic tanks or WWTP

Waquoit Bay Participants

- Risk Assessment Team
  - Boston University
    University of Connecticut
  - Waquoit Bay National Estuarine Research Res
  - EPA ORD NCEA staff

- Risk Managers
    Waquoit Bay National Estuarine Research Res
  - Cape Cod Commission
  - Association for the Preservation of Cape Cod
  - MA DEP, F&W, CZM
  - Towns of Mashpee & Falmouth

Clinch & Powell River

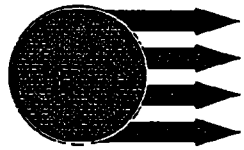
Site	2900 sq mi- VA freshwater fish, mussel species diversity
Stressors	sediments & toxins
Effects	fish & mussel species
Scientific Approach	GIS to compare land use with fish & mussel data
Mgt Decisions	ESA, CWA

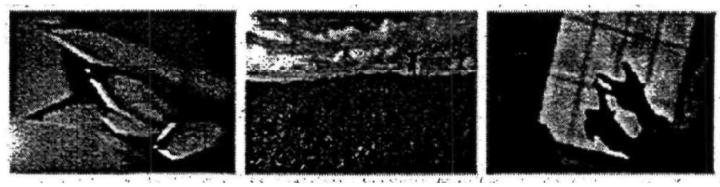
Messages (cont.)

- The scope of a complex risk assessment should be determined by risk management goals and risk priorities.
- Conceptual models clarify priorities for data collection, assessment, and RM decisions.
- Stakeholder input (regulated, affected or interested parties) should be early, but process is needs more guidance.

Planning and Scoping Outputs for Cases

- A list of stressors, sources, and assessment endpoints for each case showing what is in and what is out with rationale
- Conceptual model and text on hypothesized linkages between stressors and effects
- An analysis plan for the assessment.





Training-Exchange provides a range of training information to EPA, other federal agency, state, tribal, and local staff involved in hazardous waste management and remediation. The site includes training schedules fot hundreds of deliveries of more than 65 classes.

Training Coordinators, On-Scene Coordinators (OSCs), Remedial Project Managers (RPMs), Permit Writers, Corrective Action Managers, Site Assessment Managers (SAMs), Enforcement staff, Community Involvement Coordinators (CICs), State Program Managers, and others will find training courses and information directly targeted to their needs.

EPA HOMEPAGE | TRAINING-EXCHANGE HOME
Privacy and Security Notice
Email: pachon.carlos@epa.gov

Training Exchange Homepage
Last Modified: 07/06/99 11:00:57
URL: http://trainex.org/content.htm

http://trainex.org

FEDERAL ADVISORY COMMITTEE ACT
DISCUSSION SCENARIOS

SCENARIOS INVOLVING WHETHER TO CHARTER A COMMITTEE

1. Management officials of the EPA program office are planning a public meeting to review a strawman of the "dimethyl-chickenwire" rule. Notice of the public meeting has been published in the Federal Register and specific interested parties have also been personally invited by EPA to attend the meeting. EPA's agenda for the meeting will include presentations by the EPA of the strawman, and presentations by various known interest groups on their views. A period of open public comment will be held before the meeting is concluded.

Is this meeting subject to FACA?

What precautions should be taken to protect the integrity of the Agency's process?

2. Management officials of the EPA program office were so pleased with the range of responses at the public meeting discussed above that they have decided to conduct a series of three "round-table" discussions with the most active parties who spoke at the public meeting. EPA's agenda for the round-table meetings includes presentation of a revised strawman rule and presentations by the various interest groups on their views with regard to the revised strawman. While the meeting is primarily by invitation and a table will be set up to seat the Agency and interest groups, no one will be turned away who shows up. The agenda will allow time for members of the audience to speak The stated purpose of the meetings is to obtain facts and to exchange information with the parties. The roundtables will be held in three different locations. The agenda for each of the round-tables will be the same in each city. The invited attendees will be from the same interest sectors but not necessarily the same individuals or organizations.

Are these meetings subject to FACA?

What precautions should be taken to protect the integrity of the Agency's process?

3. Management officials of the EPA program office were pleased with the results of the round-table meetings. Further development of the strawman rule rests on exploring technical options in more detail with the interested parties. EPA has decided to hold three more round-table meetings, each focusing on a different technical issue with the goal of fleshing out the options more thoroughly. Most of the invited attendees will be the same at each meeting. Notice of the meetings will be published in the Federal Register. There will be a plenary session with several smaller breakout sessions for more interactive discussion. EPA's agenda will include time for

the audience to speak at the end of the round-table session. While the stated goal of the sessions is to obtain facts, generate a list of options and exchange information, the Agency does not want to discourage the parties from narrowing down the options; however the Agency does not intend nor expect the group to reach a consensus.

Are these meetings subject to FACA?

What precautions should be taken to protect the integrity of the Agency's process?

4. Management officials of the EPA program office have tasked a facilitation and meeting support contractor to obtain input from outside stakeholders on the implementation of the "dimethyl chickenwire" emissions rule. The contractor will identify appropriate stakeholders to be members of a group that will meet several times to review the Agency's program implementation. EPA will give the contractor a list of groups who have been involved in the past on the issue of dimethyl chickenwire who might be appropriate group members. The contractor and the group members, with input from EPA, will jointly draft meeting agendas and will jointly decide on information to be gathered and discussions to be held. The meetings of the group will be open to the public and EPA will announce the meeting schedule in the Federal Register. EPA will attend all of the meetings of the group and will sit at the table and be an active participant in the discussions.

Is this group subject to FACA?

What precautions should be taken to protect the integrity of the results of the discussions for EPA's use?

SCENARIOS INVOLVING CLOSING OF MEETINGS AND PROTECTION OF DOCUMENTS

The following scenarios assume that EPA has chartered a FACA committee to negotiate the emissions standards for "dimethylchickenwire".

5 Three members of different interest sectors of the FACA Committee to Negotiate Dimethyl-chickenwire Emissions agree among themselves to meet over lunch to discuss golf scores, vacation plans and the issues to be addressed at the next plenary meeting of the Committee.

Is this meeting subject to the meeting notice and openness provisions of FACA?

6 The industry members of the Committee to Negotiate Dimethylchickenwire Emissions decide to hold a caucus meeting to discuss their responses to the emissions control options discussed at the last plenary meeting.

Is this meeting subject to the meeting notice and openness provisions of FACA?

7 The state, environmental and EPA representatives on the Committee to Negotiate Dimethyl-chickenwire Emissions decide to hold a joint meeting independent of direction from the Committee to draft a strawman options paper to be presented at the next plenary meeting of the Committee.

Is this meeting subject to the meeting notice and openness provisions of FACA?

8 The Committee to Negotiate Dimethyl-chickenwire Emissions appoints a workgroup to draft a strawman options paper to be presented at the next plenary meeting of the Committee.

Is a meeting of this workgroup subject to the meeting notice and openness provisions of FACA?

9. During the plenary meeting of the Committee to Negotiate Dimethyl-chickenwire Emissions, a break is called for so that various interest groups can caucus with their members and constituents.

Must these caucus meetings be subject to the meeting openness provisions of FACA?

10. During the plenary meeting of the Committee to Negotiate Dimethyl-chickenwire Emissions, the Committee decides to break into workgroups. Each workgroup is tasked with a different subject to gather more information and to construct a list of options and recommendations. According to the Committee's protocols, the workgroups are made up of both Committee members and other subject matter specialists.

Must these workgroup meetings be open to the public?

11 The Committee to Negotiate Dimethyl-chickenwire Emissions has drafted up a very sensitive recommendations paper which will be discussed at the next committee meeting. There is considerable concern that to make this document public before the Committee has finished its deliberations would hurt the economic standing of the regulated industry.

Can the Committee close this meeting to the public?

12. The Committee to Negotiate Dimethyl-chickenwire Emissions needs to review certain confidential business information in order to begin work on its recommendations. This information is best presented in a meeting of the Committee members so that the members can ask questions and challenge assumptions together.

Can the Committee close this meeting to the public?

13. Members of the Committee would like to present information to the Committee on the technology developments and costing information relating to emerging technology. Some of this information is likely to be confidential business information.

How should the information be presented?

Does the presentation and consideration of this information create an antitrust concern?

14. The Committee to Negotiate Dimethyl-chickenwire Emissions has almost completed its work on its recommendations to the Agency. An outside party has sent a letter to the facilitator requesting a copy of the latest document.

Can the Committee deny the request for the previously unreleased draft document?

15 The Agency has presented a draft rule to the Committee for its consideration. The draft rule has not been released outside of the Agency and the Committee has not received the document in plenary session. The facilitator has received a request for a copy of the draft document sent to the Committee members by a person who is not a member of the Committee.

Can the Committee deny the request for this document? Can the Agency deny the request for this document?

SCENARIOS INVOLVING COMMUNITY ADVISORY GROUPS OR RESTORATION ADVISORY BOARDS

17. Our town, USA has a Superfund site that involves emissions of dimethyl chickenwire. Citizens and elected officials in the community have separately approached the EPA regional office regarding the interest of the community in taking a more active role in expressing their opinions to EPA regarding how the site should be dealt with. The EPA Community Involvement Coordinator has met with a number of these groups and has suggested that they form a Community Advisory Group that would be a primary contact group for EPA in the community regarding exchange of information, data and opinions regarding the site. A local minister has taken the lead in forming the group which has members from local neighborhood associations, the Chamber of Commerce, a local environmental group and some concerned individuals. EPA officials are often invited to attend and observe or speak at the CAG meetings.

Is this group subject to FACA?

Do any of the following situations change this?

What if the group applied for and received a Technical Assistance Grant (TAG) from EPA?

What if the Regional office provided the assistance of a facilitator on contract to EPA to facilitate meetings of the CAG?

What if the group reviews the RI/FS and makes a consensus recommendation on the remedy to EPA?

Do the meetings of the CAG have to be open meetings, announced in advance?

Does the CAG membership have to be balanced?

18 A primary manufacturer of dimethyl chickenwire, Bob's Chemicals, is interested in making an application to EPA for consideration in Project XL. The project would involve changes in the manufacturing process for dimethyl chickenwire that would require some flexibility in compliance measures under the dimethyl chickenwire emissions rule. In order to present a

successful project proposal, Bob's Chemicals must design and initiate a significant and effective stakeholder involvement process in the community surrounding its facility. The EPA regional office offers some advice on whom to contact in the community and gives the company some background documents on design of effective stakeholder involvement programs. Bob's Chemicals follows EPA's advice and contacts community members and eventually forms a Community Advisory Panel to participate in design of the Project XL Project Agreement.

Is this group subject to FACA?

SCENARIO INVOLVING PUBLIC INVOLVEMENT IN SETTLEMENT OF AN ENFORCEMENT CASE

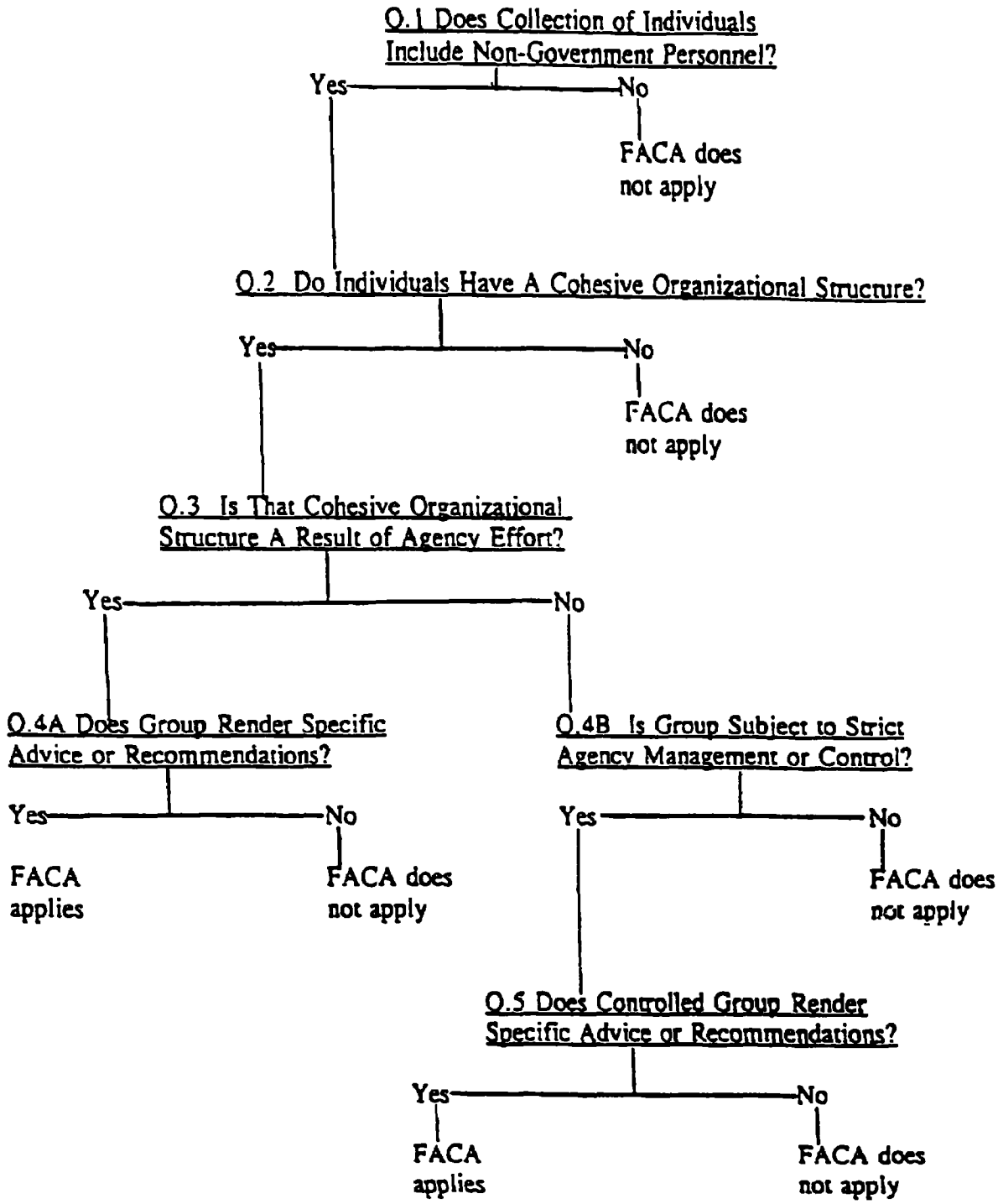
The following scenario involves a Superfund enforcement settlement action.

16. The EPA has assembled a group of Potentially Responsible Parties (PRPs), local citizens and state and local officials to discuss contamination and risk studies at a local Superfund site in preparation for settlement negotiations. The initial goal of the group is to identify data gaps that must be addressed to begin negotiations on the remedy. After identifying the issues and data gaps, the group progressed to form a coordinating council to develop the scope of the Remedial Investigation/Feasibility Study (RIFS), and then to supervise the completion of the studies. Once the studies are completed the coordinating council will make recommendation on the remedy to be incorporated into a consent decree.

Is this coordinating council subject to FACA?

What precautions should be taken to protect the integrity of the Agency's decision making process?

FACA QUESTION TREE



The term ADVISORY COMMITTEE means

any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee") which is –

(A) established by statute or reorganization plan,

or (B) *established or utilized* by the President

or (C) *established or utilized* by one or more agencies,

in the interest of obtaining

advice or recommendations

for the President or one or more agencies or officers of the Federal Government,

EXCEPT THAT such term excludes

(i) the Advisory Commission on Intergovernmental Relations,

(ii) the Commission on Government Procurement,

and (iii) any committee which is composed WHOLLY of FULL-TIME officers or employees of the Federal Government.

FEDERAL ADVISORY COMMITTEE ACT, 5 U.S.C. App. § 3(2)