

## **Improving EPA Scientific Assessment Practices for Decision Making**

### **SAB Charge for a New Study**

Effective human health and environmental protection requires a strong foundation of scientific knowledge and EPA therefore uses many kinds of scientific assessments for policy analysis and decision making. EPA decisions about managing risks to human health and the environment are supported by human health and ecological risk assessments, socioeconomic analyses, and other kinds of environmental assessments. Examples of such EPA decisions include determining permissible release levels of toxic chemicals, granting permits for hazardous waste treatment options, and selecting methods for remediating Superfund sites. To ensure that EPA's assessments use the best appropriate available science and meet the increasingly complex information needs of decision makers, the Agency has requested that the Science Advisory Board undertake a study of how EPA can strengthen scientific assessment practices for environmental decision making (attached memorandum from EPA Administrator to SAB Chair, October 20, 2008).

As discussed below, previous studies conducted by the Science Advisory Board (SAB) and the National Research Council (NRC) have found that improvements in EPA's risk assessment and decision making processes are needed to ensure that the best and most relevant information is available for use in decision making. This new SAB study will build upon findings and recommendations of these previous studies.

### **SAB Report, *Toward Integrated Decision-Making***

In the report, *Toward Integrated Environmental Decision-Making* (EPA Science Advisory Board, 2000) the SAB found that an integrated approach to decision making is needed to effectively address new and complex environmental problems. The SAB noted that such an integrated approach involves a holistic assessment of environmental problems that incorporates traditional human health and ecological science assessments, socioeconomic analyses, use of decision science tools, and methods for assessing cumulative risk. The SAB proposed that EPA adopt a three-phased approach to risk assessment and decision making. In phase I (problem formulation), EPA would conduct preliminary analyses to compare risks and establish goals, and also conduct preliminary analyses of risk reduction options. In phase II (analysis and decision making), EPA would conduct an in-depth analysis of risks and projected risk reduction under possible management scenarios. A preferred risk reduction option, or set of options, would then be selected based upon criteria such as feasibility, cost-effectiveness, seriousness of risks addressed, and equity. In phase III (implementation and performance evaluation), preferred management options would be implemented, and environmental results would be monitored and evaluated. Such monitoring would provide feedback needed to modify and adapt management approaches as necessary. The SAB suggested that the proposed framework would help EPA decision makers consider the trade-offs required to achieve multiple, often competing goals, and select appropriate risk management options.

## **SAB Advice on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making**

In the report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board* (U.S. EPA Science Advisory Board, 2008), the SAB found that EPA could advance the practice of ecological risk assessment for use in decision making by developing new methods and tools to consider such issues such as temporal and spatial scale, biological complexity, and cumulative risk. The SAB also found that the practice of ecological risk assessment could be advanced by: 1) encouraging problem formulation dialogue between ecological risk managers, assessors, and stakeholders, and considering specific management alternatives during problem formulation; 2) linking specific testable hypotheses and questions to management information needs, data collection, and analysis; 3) aligning decision and supporting risk and economic analyses with “what matters to people” by increasing the understanding of and capacity to utilize ecosystem valuation methods in conjunction with decisions; 4) identifying uncertainties that may affect the quality of risk management decisions, and addressing uncertainty in a manner that allows trade-offs in risk management alternatives to be evaluated and communicated to the public; and 5) initiating post-decision audit programs to evaluate the environmental outcomes of risk-based decisions.

## **National Research Council Report, *Science and Decisions: Advancing Risk Assessment***

In the 2008 report, *Science and Decisions: Advancing Risk Assessment* (National Research Council, 2008) the NRC found that EPA needed a more coherent, consistent, and transparent risk assessment process to address the complexities of current problems and potential decisions, and ensure that the best available options for managing risks are considered. The NRC provided the following key recommendations to strengthen the risk assessment process.

- To improve the utility of risk assessments, EPA should adopt a three-phased framework for risk-based decision making. In phase I (enhanced problem formulation and scoping) available risk-management options would be identified. In phase II (planning and assessment) risk assessment tools would be used to determine risks under existing conditions and under potential risk management options. In phase III (risk management), risk and nonrisk information would be integrated to inform choices among options and make decisions.
- EPA should focus increased attention on the design of risk assessments (e.g., planning, scoping, and problem formulation) to ensure that assessments are more useful to and better accepted by decision makers. In this regard, the NRC recommended that risk assessments include a design stage that is more aggressively focused on informing decisions. The NRC specifically recommended more effective consideration of the potential for risk assessment processes to contribute to unintended consequences such as delays in risk-based decisions that may prolong exposure to risk, and divert attention

away from other important risks within EPA's mandate. In addition, the NRC recommended consideration of the potential for uninformed risk-risk substitutions.

- EPA should address a number of institutional and management issues in order to improve risk assessments. The issues include: 1) the need for proactive identification of studies and data that are most relevant to current risk assessment needs and effective communication of the need for such studies to the research community; 2) hiring needs for additional staff in fields such as epidemiology and quantitative uncertainty analysis important to improving EPA's scientific assessments, and ways to attract and retaining technical staff in these areas; 3) the need to establish and maintain risk assessment and decision-making training programs for scientists and managers responsible for risk assessment activities; 4) the need to expand EPA interoffice and interagency collaboration on risk assessments that support decision making and reduce the effects of compartmentalization resulting from EPA's organization around diverse statutory mandates; 5) the need to expand the scientific and decision-making core in the Agency's regional offices to ensure that they have the capacity to use improved risk-assessment methods to meet obligations for interaction with stakeholders, local agencies, and tribes; and 6) the need to effectively implement existing risk assessment guidelines, revise existing guidelines, and issue supplemental guidance as well as new guidelines.
- EPA should improve the characterization and communication of uncertainty and variability in all key computational steps of risk assessments. In this regard, the NRC recommended that EPA adopt a tiered approach for selecting the level of detail used in uncertainty and variability assessment.

### **Proposed New SAB Study**

The new SAB study will evaluate the extent to which EPA's scientific assessment practices are integrated into environmental decision-making practices as previously recommended by the NRC and the SAB. The study will focus on EPA's application of scientific assessments in environmental decisions concerning chemical and microbial pollutants. The SAB will identify barriers to implementing NRC and SAB recommendations and suggest immediate and future actions that EPA could take to develop and institutionalize integrated environmental decision-making. Areas of consideration may include scientific leadership, scientific practices, scientific collaboration across disciplines, and scientific expertise and workforce. The SAB may also make additional recommendations, beyond those previously provided by the NRC and SAB, to improve the integration of EPA's scientific assessments for decision making.

To conduct this study, a new *Ad Hoc* Committee will be formed under the auspices of the SAB. The Committee will be comprised of selected members of the chartered SAB and Standing Committees. The Committee may be organized in subgroups to address different kinds of scientific assessments conducted by the EPA (e.g., human health risk assessments, ecological risk assessments), and/or different kinds of environmental decisions under various EPA programs. The Committee will be chaired by a member of the chartered SAB and supported by a team of SAB staff serving as Designated Federal Officers.

The Committee will hold an initial public meeting to develop a study plan. Subgroups of the Committee will hold informal discussions with EPA offices to conduct fact finding and gather background information as needed. The Committee will conduct a public workshop to seek input from EPA representatives, stakeholders, and interested members of the public and formulate its findings and recommendations. Following the workshop the Committee subgroups will prepare sections of the Committee’s advisory report. The Committee will then hold a public meeting to discuss the subgroup findings and prepare its draft advisory report. The Committee’s draft report will be then submitted to the chartered SAB for a quality review and approval at a public meeting.

**Project Time Frame**

Milestone	Approximate Time to Complete Milestone
1. Development of the SAB Proposal.....	February - May, 2009
• Approval of Proposed new SAB study	
• Formation of Committee	
2. Development of Committee Study Plan .....	June - July, 2009
3. Fact Finding and Planning for Public Workshop .....	August – December, 2009
4. Conducting a Public Workshop.....	January, 2010
5. Development of Public Draft of Advisory Report.....	February - March, 2010
6. SAB Quality Review of the Committee Report.....	April - May, 2010
7. Publication of SAB Report.....	June, 2010

**References**

National Research Council. 2008. *Science and Decisions: Advancing Risk Assessment*. National Academies Press, Washington D.C. [Available at: [http://books.nap.edu/openbook.php?record\\_id=12209&page=R1](http://books.nap.edu/openbook.php?record_id=12209&page=R1)]

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 20 2008

THE ADMINISTRATOR

**MEMORANDUM**

**SUBJECT:** Request for a Science Advisory Board Study

**TO:** Dr. Deborah Swackhamer  
Chair, Science Advisory Board

At the U.S. Environmental Protection Agency, sound decision-making depends on getting the best available science. During its 30-year history of advising EPA Administrators, the Science Advisory Board has emphasized the need for anticipating future environmental threats and investing in emerging research and science critical for informing decisions. As our understanding of complex environmental problems improves, integrated approaches for delivering the best science need to be developed and implemented.

The SAB's 2000 report *Toward Integrated Environmental Decision-Making* suggested an integrated decision-making framework for evaluating and responding to environmental problems. I ask that the SAB initiate a study that builds on its 2000 study to develop independent advice on how EPA can strengthen scientific assessments for decision making. The SAB might consider EPA's organizational structure and functions in light of how they influence the development and application of science assessments in different decision-making contexts. It would also be valuable for the SAB to recommend how to strengthen EPA's approaches for integrating traditional human health and ecological science assessments with socioeconomic analyses, decision sciences, and technology development and assessments to better support policy development. Finally, as EPA continues to plan for human capital needs, I would like the SAB to provide advice on ways to attract and retain the best diverse technical workforce.

Attached is a brief description of the proposed study. Please feel free to tailor the scope and depth of the study as appropriate. I ask the study be completed in a timely manner for the next EPA Administrator's consideration and implementation.

A handwritten signature in black ink, appearing to read "S. L. Johnson".

Stephen L. Johnson

Attachment

Effective human health and environmental protection requires a strong foundation of scientific knowledge. Scientific information often includes considerable uncertainty resulting in a diversity of scientific interpretations. The development and application of scientific knowledge in identifying potential threats, characterizing risks, formulating technological solutions, and evaluating the benefits and costs of U.S. Environmental Protection Agency actions are major science functions at EPA. The scope and depth of such science assessments greatly vary under different legislation and policies.

These functions are carried out by scientists, engineers, and economists with specialized program knowledge. They, in turn, rely on technical support by outside experts procured through Agency's interagency agreements or contracts. In addition, EPA's National Center for Environmental Assessment in the Office and Research Development develops technical assessments for EPA's Integrated Risk Information System which are used throughout the Agency. Summaries of the potential human health effects information that may result from exposure to chemicals in the environment, along with the supporting Toxicological Reviews, are made available electronically on IRIS for use by EPA, states, and tribal governments.

Over the years, reports from the National Research Council, the General Accountability Office, and other organizations point out that, while EPA has knowledgeable experts, the Agency's policies and regulations are too often perceived to lack a strong scientific foundation and EPA's science is of uneven quality. To address these issues, EPA established several science coordinating bodies. For instance:

- the Risk Assessment Forum consists of Agency senior scientists that develop Agency-wide technical guidelines for human health risk assessment, ecological risk assessment, and exposure assessment;
- the Science Policy Council develops Agency position papers on cross-cutting and emerging issues (e.g. peer review practices, data quality guidelines, genomics, nanotechnology); and
- the Council on Regulatory Environmental Modeling guides the development and use of environmental models.

Staff support for these coordinating bodies is now centralized in the newly created EPA Office of the Science Advisor. In addition to these groups, the National Regional Science Council promotes communication and collaboration of regional scientists to identify common regional needs.

Nonetheless, scientists, engineers, economists, and other technical professionals, by necessity, continue to be spread throughout the Agency and have limited opportunity to interact with their peers in other organizational units. Such segregation can result in duplication of effort as well as conflicting scientific approaches to the evaluation of similar environmental agents by different offices. While the Agency has tried to minimize such occurrences through its science and science policy coordinating bodies, existing coordination processes can be slow and tend to occur in the later phases of assessment development and approval. Furthermore, the environmental problems of today are more complex, often cross state and national boundaries, and require consideration of difficult trade-offs and integration of socioeconomic and technological solutions. EPA's existing science and science policy coordinating bodies primarily address immediate scientific needs of the Agency and may miss a longer-term strategic viewpoint.

## **Proposal**

The SAB has provided scientific advice and recommendations to the Agency on a wide variety of scientific issues for more than 30 years. Because of the SAB's unique perspective, it would be of value for the SAB to evaluate the Agency's current organizational structures and functions concerning the development and application of science assessments in different EPA decision-making contexts. The evaluation would result in advice and recommendations on how the Agency might strengthen scientific assessments, communication of uncertainties of the assessments, and how the results are used. Areas for consideration may include: scientific leadership; consistent scientific practices; scientific collaboration within and between disciplines; and multi-disciplinary approaches for integrating natural science assessments with economic and social science assessments.