

Front-Loading Managers' Input in the Risk Assessment Process Issues and Concerns

by Steve Gibb

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The call for earlier involvement of environmental risk managers in the design of risk assessments is one of the recommendations of the National Research Council's (NRC) 2008 report,¹ *Science and Decisions: Advancing Risk Assessment*, that is stirring debate and discussion. Part of the debate stems from differing views on the appropriate nature of the interaction between risk assessors and risk managers. The second portion of the debate has been sparked by the NRC committee's call to evaluate risk management options during the risk assessment and possibly before risks have been fully evaluated.

The committee invested considerable thought in re-conceptualizing the design of risk assessments to ensure that their scope and complexity are consistent with the needs of decision-makers. Specifically, the report encourages risk managers to place greater focus on “planning and scoping” and “problem formulation,” as outlined in the U.S. Environmental Protection Agency’s (EPA) guidance for ecological and cumulative risk assessment.^{2,3} Together with assessors and stakeholders, risk managers participating early in the process “can evaluate whether the design of the assessment will address the identified problems,” and see risk assessment “as a method for evaluating the relative merits of various options for managing risk.”

As a matter of first impression, these recommendations make a lot of sense. Highly technical and costly risk assessments should be more relevant to decisions that affect environmental and human health, the economy, and interest groups. However, observers inside and outside EPA are warning that these recommendations have the potential to propagate political interference—a longstanding concern voiced in previous NRC reports and by EPA scientists. In addition, the observers point to an inherent problem in establishing risk management options before the types and magnitude of the risks are known. They say that customizing risk assessments in the way envisioned by the NRC committee could both dramatically advance the field by improving decisions in some circumstances, but also limit the applicability of risk assessments elsewhere.

Thumb on the Scale?

At the 2008 Society for Risk Analysis (SRA) annual meeting, Dr. Peter Preuss, the director of EPA’s National Center for Environmental Assessment, reported that his organization is hampered by inappropriate overinvolvement on the part of political risk managers. Dr. Preuss oversees EPA’s database of chemical toxicity values, the Integrated Risk Information System (IRIS), a resource that is relied on by state and regional officials and other environmental professionals for hazard and dose-response information on select chemicals. Dr. Preuss urged the Obama administration to “get rid of” the Bush administration’s process for reviewing EPA chemical toxicity assessments, charging that

the process was politicized and led to delays.

While some agree with Preuss that giving risk managers a greater role in planning or overseeing toxicity reviews presents opportunities for political interference, others see a legitimate role for the White House Office of Management and Budget (OMB) and other agencies to have input on toxicity assessments such as IRIS files. Jim Solyst of Environ wrote recently that, “Federal agencies that are regulated parties should have the opportunity to contribute information and expertise. . . OMB is obligated to review agency-issued guidance and IRIS assessments are certainly guidance.”⁵

Other writers have examined the history of allegations of political manipulation of environmental science and the willingness and/or ability to bend or ignore the scientific findings of federal agency experts in establishing environmental policies.^{6,7} Similar to past administrations, the scientific integrity of agency actions has been highlighted as a priority issue that President Obama addressed in a March 9 memo to agency heads.⁸ How the Obama administration balances science with politics, especially in the wake of charges that Bush appointees exerted unprecedented influence over federal scientists, will be revealing.

The role that politics plays in science-based policy proposals will likely continue, in part, because the interpretation of the gray areas in which there is little or no scientific consensus is defined by the political stripe of the beholder. However, as many past NRC panels and others have emphasized, steps can be taken to ensure that a “semi-permeable” membrane exists between risk managers and scientists to protect the risk assessment process from scientifically unfounded manipulation, while allowing the exchange of pertinent information on key challenges and knowledge gaps.

As Jim Aidala, EPA Deputy Associate Administrator for the Office of Prevention, Pesticides, and Toxic Substances during the Clinton administration, once phrased it, “who is in the sandbox and how they play” can be carefully structured. Risk managers can provide input in the planning steps without unduly biasing the types of assumptions and scientific questions that are employed and pursued.

'Every review my group does has to go to the OMB three times . . . and OMB has de facto veto over science. The process has gotten terribly politicized . . . and is an illustration of how the scientific process can be manipulated for political purposes.'⁴

>>Dr. Peter Preuss
National Center
for Environmental
Assessment

In fact, there may be good reasons to believe that utilizing specific "planning and scoping" and "problem formulation" processes as defined by EPA and recommended in the NRC report will maintain the integrity of an effective semi-permeable membrane.

Solution-First Problems

A second NRC recommendation that is stirring new and interesting debate is the recommendation that risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk. The NRC report maintains that "risk assessment should continue to capture and accurately describe what various research findings do and do not tell us about threats to human health and to the environment, but only *after* the risk-management questions that risk assessment should address have been clearly posed." [emphasis original]¹

Observers both within and outside the agency tend to fall into three camps in response to this finding. The first see the recommendation as illogical and argue that risk managers already must follow statutory frameworks that variously require health, technical feasibility, cost-benefit, small-business impacts and other reviews that constrain them from developing management options until the magnitude and probability of the risk is assessed and understood. Although risk managers may have significant experience with the evaluation and management of contaminants in their regulatory frameworks, new assessments draw on recent data, engineering, and research and can cast potential risks in a new light depending on recent experience with regulatory effectiveness, toxicology, and exposure route and pathway information, these observers say.

The second camp sees a potential for unwarranted controversy as a distraction that may make risk managers think twice before putting their regulatory options on the table early in the process. Articulating options with stakeholders present, which may include the options "do nothing" and "stringent regulation," is good fodder for leaks and media coverage. A reporter's knowledge of the options allows them to reach deep into stakeholders' pressure points and elicit reactions that could stir

controversy for years before any decision is even in the offing. Many advocates are also willing to say why they care and how much it will cost them, the public, or the health status of the nation, and what they'll do next—all of which make good follow-up stories.

The third camp is concerned that resources sunk into an assessment that addresses a very narrow set of options and circumstances might not be transferable to other situations risk managers face. Limiting the scope of the risk assessment may reduce its usefulness and applicability to others. For example, if EPA were to assess options to mitigate indoor air-based formaldehyde risks in trailers used to house displaced persons after Hurricane Katrina, would the results help underpin national air toxics standards for formaldehyde emitted from pressed-wood factories? When risk assessments are tailored to specific problem sets and circumstances, the immediate decision may be served extremely well, but there may be a tradeoff that erodes the common applications of these types of assessments elsewhere.

All Eyes on IRIS

At the opposite end of the spectrum of highly-tailored assessments are the most intentionally generic ones, the toxicity assessments/dose-response analyses that reside in EPA's IRIS database. Although these are not full risk assessments that include exposure and risk characterization information, they are prevalent components of full assessments. The database originated out of the chaos of individual EPA programs each developing their own toxicity values. IRIS became a way to develop consistent intra-agency chemical toxicity values so that EPA air, waste, water, and toxics managers at every level could draw from single reference points. The database then went external and inter-agency and is now relied on extensively at all levels of government, by engineers, scholars, consultants, and environmental professionals, and even internationally.

For a variety of reasons the IRIS program has slowed in both generating new and updating existing chemical risk values. This has limited the pool of available toxicity assessments, sending multiple states scrambling to develop their own

toxicity values for chemicals such as trichloroethylene, formaldehyde, and dioxin. It remains unclear how IRIS program managers will implement the NRC recommendations and gather input from risk managers for “planning and scoping” and “problem formulation.” Currently, IRIS program managers meet with EPA’s waste, water, and air programs to ascertain their needs and what level of complexity they are seeking in a chemical risk review, but seeking more outside input may challenge a program seeking to streamline its process by extending the time and energy required at the start of the assessment. It would be “a whole new world for us,” according to one EPA official, and Dr. Preuss spoke less than enthusiastically about the prospect at SRA.


Conclusion

As an environmental risk manager, or someone who advises one, you may be asked to plan and formulate key risk problems going forward by a select team launching a new risk assessment. Adhering to the relevant sections on planning and scoping and problem formulation in EPA’s documents and the NRC report may help inoculate you against charges of political interference.

But there are larger issues and implications at stake worth considering as you or your principal decision-maker plans and formulates. Can the assessment be tailored to risk management options that are likely to be relevant whatever the findings of the risk assessment? Can the assessment be focused to suit some circumstantial details for the decisions ahead yet maintain enough generality so colleagues seeking a resource in related decisions can also find it useful? Would securing promises of confidentiality from stakeholders invited to participate in planning and scoping and problem


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formulation processes enhance the discussion and prevent pre-decisional public dissension?

The NRC has recommended that risk assessments be designed in ways that could dramatically advance the quality of decisions in certain circumstances and improve the utility of risk assessment as a tool. Maintaining a dynamic balance between specific decision needs and replenishing the pool of assessments to which colleagues can turn is key to efficient use of the resources invested in risk efforts. **em**

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