

# Risk Policy Report

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## EPA Framework Emphasizes Risk Management Options In Assessments

A work group of EPA's Risk Assessment Forum (RAF), a group of risk assessors, is drafting a new framework that includes expanded consideration of risk management concerns at the front end of a risk assessment - a controversial recommendation in the National Academy of Sciences (NAS) 2008 report, "Science and Decisions: Advancing Risk Assessment."

A draft diagram of the new framework, presented at a workshop earlier this month, suggests the agency is weighing consideration of risk management options for the first time during human health risk assessments, a practice the agency has so far only conducted explicitly during ecological risk assessments.

In its report, the NAS urges EPA to perform extensive scoping in the first phase of human health risk assessments, considering risk management options up front. But the approach is a hotly debated one, as some risk assessors, including some at EPA, argue that such considerations lead to politicization of risk assessments.

EPA last year began considering a new process for human health risk assessments based on existing guidance for ecological risk assessment in an effort to implement the NAS recommendations (*Risk Policy Report*, Nov. 16).

Now EPA is floating a new framework that suggests the agency is moving forward with efforts to implement the approach. For example, the framework suggests that risk assessors consider "If existing conditions may pose a threat to human health, what are options to alter those conditions?" and "What are the management goals and decisions needed?" during the initial scoping phase of the risk assessment, according to a presentation from an agency official earlier this month.

A diagram of a draft version of the new framework appears similar to a schematic in the NAS report, which describes the diagram as "a framework for risk-based decision-making that maximizes the utility of risk assessment."

Rita Schoeny, science adviser to EPA's water office, laid out some of the details of the new framework during a keynote presentation at the third Beyond Science and Decisions workshop in Falls Church, VA, May 4-6, where risk assessors are seeking to address some of the same NAS report's recommendations on dose response analysis.

Schoeny, one of the agency assessors leading the effort, described the framework as "a work in progress. Not yet the policy of EPA, though I think it will be soon." *The diagram is available on InsideEPA.com. (Doc ID: 2364751)*

Schoeny noted that her group's draft framework, like NAS, separates "the process into three parts: planning and scoping, risk assessment and considerations for informing decisions - because risk assessors don't do risk management." The NAS' diagram's third section is risk management.

The EPA framework does include some elements in its scoping phase that NAS did not, including: "What legal / statutory requirements affect risk management options and the level of analysis required? Are there environmental justice or life stage considerations that affect risk management options? What resources are available to conduct the assessment?"

Environmental justice and children's health are priorities for EPA Administrator Lisa Jackson, issues she asked the RAF to include in its discussions when the group gathered 100 risk assessors from across the agency in an internal colloquium last fall to discuss documents the agency intends as its response to NAS.

**At the May workshop, Bette Meek, a professor at the University of Ottawa, asked Schoeny** why there is the perception that EPA does not do problem formulation before its risk assessments, because agency risk assessors "clearly do problem formulation," Meek said.

Schoeny replied that agency practices in this regard have not been formal. "A lot of us took umbrage at the Silver Book" criticisms that EPA does not do problem formulation. The response was, "What are you talking about - of course we do that," Schoeny said. But she added that "We need to make more explicit the process" of problem formulation.

The second phase of the process, risk analysis, begins with problem formulation, which Schoeny detailed in her remarks. This is the "part of the planning process that systemically identifies the major factors to be considered in a particular assessment," according to Schoeny's presentation. She added that it "Draws from the regulatory and policy

context of the assessment” and “Provides the foundation for the technical approach of the assessment.”

The framework indicates that problem formulation should include both a conceptual model and an analysis plan. Schoeny indicated that this phase of the new framework is informed by an RAF document on ecological risk assessment published in 1998. Sources said last fall that officials discussed the eco risk approach at the RAF colloquium, because it also starts with an extensive planning and scoping section at the beginning of its risk assessment process, which has not traditionally been part of the human health risk assessment process.

The conceptual model “Describes actual or predicted relationships between humans (or populations or population segments) and the chemicals or other stressors to which they may be exposed,” according to Schoeny’s presentation. She added that the analysis plan explains how the assessment will be performed. The plan should include descriptions of the approach, data and models to be used, as well as descriptions of existing data gaps.

Lastly, the framework asks risk assessors to consider a series of questions when the assessment is completed, including some sticky questions, such as “What is the public health protection provided by the proposed option?” and “How are other factors (technologies, costs, social considerations, environmental justice, sustainability, etc) affected by the proposed options?” The framework also asks the difficult question often faced by EPA assessors performing Integrated Risk Information System (IRIS), “Will the outcome change if the data are interpreted differently?”

Schoeny added that in the process of drafting the framework the group has learned that “many plans and conceptual models can benefit from peer review . . . We don’t have to do new problem formulation for every risk assessment, we can have a standard operating procedure.” She added that the “benefits of transparency are worth the effort” in creating the plan, leading to “better tailored risk assessment,” one that is also “better accepted” by stakeholders and the public.

Schoeny noted that other benefits of the formalized planning process is that “explaining the rationale for decisions makes for an objective scientific dialogue” between the agency and stakeholders who may disagree with decisions in an agency risk assessment. And she noted that “fit for purpose” risk assessments are “a good thing. “A risk assessment that is not useful should never have been done in the first place.” - *Maria Hegstad*