



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

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June XX, 2007

EPA-SAB-07-XXX

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

SUBJECT: Science Advisory Board's Homeland Security Advisory Committee
Consultation on the EPA's Emergency Consequence Assessment Tool and
Incident-based Microbial Risk Assessment Framework

Dear Administrator Johnson:

The Science Advisory Board (SAB) Homeland Security Advisory Committee (HSAC) held a public meeting on May 30 and 31, 2007 to provide consultative advice on the Agency's Emergency Consequence Assessment Tool (ECAT, September 2006) and the Draft White Paper on Incident-based Microbial Risk Assessment Framework (MRA, May 2007). The HSAC, augmented by additional experts from the SAB's Radiation Advisory Committee and the Drinking Water Committee, is composed of a remarkably diverse and accomplished group of experts. There was a tremendous amount of enthusiasm and energy displayed by their willingness to serve and the intensity of their involvement is a tribute to the Agency and the importance of the missions that it has undertaken for our nation's security.

The Agency has a long history of requesting early input from independent experts and the SAB welcomes the opportunity to be part of that tradition. The HSAC was very impressed by the hard and thoughtful work done by the Agency's scientists.

As this was a consultation, there will be no consensus report from the SAB. However, the HSAC would like to note several key points that arose in the consultation on these two topics. Written comments from individual Committee members are provided in the official minutes of the consultation.

Comments on EPA's Emergency Consequence Assessment Tool (ECAT)
EPA's National Homeland Security Research Center (NHSRC) within the Office of Research and Development is developing an interactive on-line risk assessment software

tool designed to provide health advisors and other emergency response officials with rapid access to critical information during an environmental emergency or training exercise. The ECAT is designed to assess and provide site-specific numeric estimates of health risks for selected chemical, biological and radiological threat agents; and identify which response actions might be appropriate to mitigate human health risks. The SAB was asked to review the preliminary version of this tool and provide advice and recommendations for its future development and application.

The HSAC offers the following thoughts regarding the ECAT:

1. The ECAT could be useful for EPA's second phase responders, risk assessors, and risk managers. It has particular promise as a training tool, if developed and evaluated according to the appropriate scientific standards (found in educational assessments, human-computer interactions, and related fields). However, its use by first responders, in the initial hours of an emergency would not be feasible.
2. The next developmental phase for the ECAT should include one or two fully developed threat scenarios. Those complete applications of the ECAT should be independently evaluated in terms of their contributions to health protection. One scenario for air contamination and one for water contamination would be good for examining generality. These demonstrations might use the Human Exposure Measurement results from the Urban Dispersion Program tracer field studies and drinking water system tracers studies.
3. For these applications, EPA should show how the ECAT's outputs will affect specific decisions. Those demonstrations should identify the impacts of specific information, accessed at specific times during a specific emergency, reaching specific decision makers, used in specific decisions, disseminated to specific audiences, interpreted in specific ways, and leading to specific protective actions. Evaluating the usefulness of information is an essential element to sound decision making and risk communication.
4. EPA should study the challenges in using the ECAT with actual events. That research should consider issues like choosing the right hazard with dissemination events (where an unknown agent is quietly introduced), determining source terms for models, and communicating to diverse audiences. The research should develop decision rules that consider the expected impacts of possible diagnoses and misdiagnoses. The research should focus on the test cases.
5. EPA should explicitly evaluate the ECAT's potential usefulness before extending it to other domains. That evaluation may conclude that some areas should be eliminated (e.g., because usable models cannot be created), that some areas are only viable if they can use data sources maintained by other organizations, that some areas can be used if their models are validated using tracer studies, and that some areas should only provide access to consulting experts.
6. EPA should develop a dissemination plan for the ECAT, addressing issues of coordination, cost, trust, liability, duplication, etc. That plan should be informed by the relevant science regarding organizational behavior, political science, and public

administration. The plan should consider selective release of the ECAT elements; for example, the collection of databases (in the left-hand toolbar) may have particular value. Risks with unintended users (both friendly and hostile) must be considered.

7. EPA needs to have a robust science program on risk communication. Scientifically sound risk communication entails identifying the information most critical to users' needs and delivering it in a demonstrably effective way. Poor communication can harm citizens, by undermining their ability to protect themselves; it can harm organizations, by undermining public faith in them. Without rigorously developed and evaluated communications, the ECAT may provide no value or negative value. The markers of sound communication science are (a) familiarity with the current research literature, (b) formal analysis of the information needs of specific decision makers facing specific decisions, (c) empirical evaluation of communication impacts, and (d) review by peers.

Comments on EPA's White Paper on Incident-based Microbial Risk Assessment Framework

EPA's NHRSC has prepared a white paper describing issues regarding the development of a decision framework for assessing health risks associated with exposure to microbial agents after an incident and developing cleanup levels associated with a decontamination response. The SAB was asked to provide advice on the development of such a framework.

The HSAC offers the following thoughts on the draft white paper:

1. The document needs clear opening statements with its strategic goals and underlying assumptions, along with concluding assessments of the sensitivity of its conclusions to those assumptions and the limits to its scope.
2. The white paper covers broad topics in very general style. Little specific assessment methodology was provided, thereby limiting the basis for comment. For example, its response parameters were too general to elicit a meaningful exchange of ideas between the HSAC members and the Agency scientists. When a more specific and detailed methodology is established, a follow-up review by the HSAC would lead to a fruitful exchange of thoughts.
3. The white paper embodies a highly simplified view of crisis management. Much more complex conditions are likely to exist and this plan must recognize them and be capable of providing flexibility to address them. Because EPA will not be leading responses in the first 24 hours, it must consider local roles and objectives. In some cases, EPA may not play a direct role in response for consequence management. Thus, clear process recommendations for use by other regulatory entities are necessary.
4. As with any risk assessment, there are numerous limitations, uncertainties, and roadblocks associated with the process. Such challenges should not be considered as insurmountable as described in the document. Rather, the EPA should write the document in a "can do manner" and deal with the limitations separately.

5. The microbial risk assessment framework should be developed to give as quantitative a measure of risk as possible, given the available data, just as one would employ when assessing chemical or food safety (also facing data limits). Sources of uncertainty should be assessed as part of risk characterization, in order to estimate the impacts of assumptions and defaults. The report should consider the risks of decontamination strategy as well as agent risk.

6. Development of background data for biological contaminants is essential and will play a central role in the development of cleanup benchmarks for various environmental settings. Background data already play a comparable role for remediation of chemical contaminants, particularly in complex environments like urban areas. Collection of background data must be an important part of the overall research agendas of EPA and other federal agencies.

7. Performance assessment of analytical methods for environmental detection of microbial agents is an area that should be given considerable attention by the EPA, however, it is not discussed in the submitted white paper. This is a critical step that follows the implementation of the remedy in the immediate-, short- and long-term.

General Comments

1. The HSAC could serve as a consultative body to the Agency as a whole in developing a scientifically sound risk communication program. The HSAC has the three essential kinds of scientific expertise: (a) domain knowledge, for many specific hazards; (b) risk and decision analysis, for identifying decision-relevant information; and (c) social science, for developing and empirically evaluating communications.

2. The HSAC could also assist the Agency in evaluating its overall homeland security research program in order to identify knowledge gaps and to strengthen future programs.

3. Much better feedback mechanisms are needed in order to take full advantage of HSAC members' expertise and to maintain their commitment. Members offered their availability for more frequent consultations, for the committee as a whole or subgroups.

Thank you for your attention and the opportunity to serve the Agency and its mission.

Sincerely,

Dr. Baruch Fischhoff, Chair
Homeland Security Advisory Committee

Dr. Rebecca Parkin, Co-Chair
Homeland Security Advisory Committee

Dr. Granger Morgan, Chair
Science Advisory Board