



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

October 26, 2004

EPA-SAB-COM-05-001

The Honorable Michael O. Leavitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator Leavitt:

On July 26, 2004, EPA offices provided a series of informative presentations to the Environmental Health (EHC) and Integrated Human Exposure (IHEC) Committees of the Science Advisory Board (SAB). The focus of the presentations was on the human health aspects of the staff paper titled, "Examination of EPA Risk Assessment Principles and Practices." The SAB would like to express its sincerest thanks to the presenters for their expertise, perspectives and insights. Their contributions greatly increased our understanding of the Agency's risk assessment policies, methods, current practices and future directions. We hope to continue working with the Agency to explore ways by which the SAB can assist in enhancing its risk assessment methods.

From these presentations and discussions, two key messages were conveyed that the SAB believes are worthy of its explicit support. The first is the Agency's stated paradigm shift that would require the use of available and relevant data instead of default assumptions; only in the absence of such data would default assumptions be invoked. This is expected to reduce the current primary reliance on default models and assumptions as the basis of decision-making. This new approach will have the benefit of encouraging data generation by the scientific community, thereby, broadening the knowledge base and potentially reducing uncertainty in risk assessment. As pointed out by EPA representatives, this shift is already articulated in the 2003 *Draft Final Guidelines for Carcinogen Risk Assessment*. As such, we strongly encourage the Agency to formally affirm its position and undertake a vigorous campaign encouraging risk assessors to adopt this new approach.

The second noteworthy area is the application of probabilistic methods which EPA rightfully acknowledges in the staff paper is a useful approach for performing hazard and dose-response assessment. The primary benefit of probabilistic assessments, like that of reducing

reliance on default factors, lies in its potential to consider all scientifically relevant data in the evaluation. This approach can provide a systematic, logical process for exploring, understanding, and describing risk. We encourage EPA to continue to promote and use probabilistic methods for not only exposure assessments but also health effects and dose-response assessments.

The SAB recognizes that implementation of these new methods will require specialized expertise. We therefore urge the Agency to provide the necessary resources in order to ensure that these improvements to the risk assessment process are successfully implemented. Again, we would like to applaud the staff for their efforts in advancing the theory and practice of risk assessment within the Agency. We look forward to working with the Agency to develop these approaches and risk assessment at EPA.

Sincerely,

/s/

Rebecca Parkin, PhD, MPH
Chair of the SAB Integrated Human Exposure
Committee and the Environmental Health Committee

/s/

William Glaze, PhD
Chair of the Science Advisory Board

NOTICE

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