



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

April 22, 1985

Honorable Lee M. Thomas  
Administrator  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

OFFICE OF  
THE ADMINISTRATOR

Dear Mr. Thomas:

A Science Advisory Board Panel met on April 9, 1985, to review the research done by the Office of Research and Development (ORD) in support of risk assessment methodology. The charge of the Panel was clear from the memorandum provided.<sup>1</sup> The Panel was asked to review the progress made by ORD in answering EPA's needs, including whether the research addresses the appropriate programmatic questions for risk assessment in EPA. Neither programs of the Office of Exploratory Research nor work done by the Research Centers Program were part of this review. In addition, the directions given to the presentors by Dr. Anderson were clear.<sup>2</sup> These were to emphasize (1) motivation for the work; (2) objectives of the individual projects; (3) intended accomplishments of the projects; and (4) how these accomplishments will help the risk assessment process in EPA.

Your staff provided a document prior to the review entitled "Research in Support of Risk Assessment." If this document is to be published, the Panel recommends that the review draft be revised and reorganized to be consistent with Dr. Anderson's memorandum (cited in the above paragraph). Overall, the major need is for an executive summary organized around the components of risk assessment, the corresponding research needs, and the way that research addresses the needs. While the document described the background for risk assessment activities at EPA, it did not provide any discussion of research needs in relation to these activities or the process of research planning to assure that these research needs will be met.

Although segments of the risk assessment research that the Panel reviewed appeared to be appropriately oriented to meeting Agency needs, the overall research program did not appear to have any coherent framework for planning and management. The amount and quality of research does not reflect EPA's stated policy on the importance of risk assessment in its decision making.<sup>3</sup> Establishing the appropriate level of risk assessment research and assuring that research will be appropriately directed to meet Agency needs requires the attention of senior management at EPA.

<sup>1</sup> Memorandum from Bernard Goldstein to Alvin Alm, "Review of Ongoing Research and Development Activities," dated October 23, 1984.

<sup>2</sup> Memorandum from Elizabeth Anderson, "Warner North's Comments on Our Agenda and Presentations," dated April 2, 1985.

<sup>3</sup> U.S.E.P.A., "Risk Assessment and Management: Framework for Decision Making," December (1984).



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The Panel believes that the present research effort will benefit considerably from (1) improved co-ordination between OHEA, OHR, and other organizational entities involved in risk assessment at EPA, and (2) a more formal research planning process. The Panel observed that high quality research was initiated through the efforts of individual researchers, but this research did not always appear clearly relevant to improving Agency risk assessment practice. There also is a tension between EPA's short-term needs for data and the time needed to establish a research group and organize the work. This will complicate the Agency's planning process.

There needs to be a mechanism for development of an Agency-wide research agenda for risk assessment. During the presentations, Dr. Roy Albert made suggestions in this regard that the Panel believes has considerable merit.<sup>4</sup> To summarize Dr. Albert's suggestions, planning of risk assessment research might involve the following four steps:

1. Identify the generic and specific knowledge gaps in Agency approaches to risk assessment.
2. Identify the relevant questions that are technically feasible to answer.
3. Analyze the impact of additional research on the risk assessment and management processes in EPA.
4. Prioritize the research according to the degree of impact on regulation, required resources, and time to complete it.

The 1983 National Academy of Sciences report on risk assessment notes the importance of coordinating the preparation of risk assessment guidelines with the identification of research needs.<sup>5</sup> While the Agency is currently carrying out an extensive effort to develop risk assessment guidelines, a parallel effort to assess research needs has not taken place.

Reviews of documents, such as the Health Assessment Documents (HADs), by the Science Advisory Board have identified a number of areas in which further research in support of risk assessment is needed, both at the generic level and with respect to specific substances. The Panel was not made aware of any formal mechanism for summarizing the research needs emerging from SAB reviews and incorporating these research needs into the planning process for EPA's risk assessment research.

- An example of a generic research need is for methodology to incorporate metabolic and pharmacokinetic information available on specific substances into quantitative dose-response assessments.
- An example of a research need on a specific substance is for additional epidemiological studies on the cohort of workers exposed to coke oven emissions. (As noted on page 14 of "Research in Support of Risk Assessment Methods," such research is underway.)

<sup>4</sup> Roy E. Albert, M.D., "Health Risk Assessment Planning: An Approach to Formulating Environmental Health Research Needs," April 9, 1985.

<sup>5</sup> National Academy of Sciences, Risk Assessment in the Federal Government: Managing the Process, Washington, D.C. (1983), pp. 171-173.

One appropriate mechanism to encourage the research needed to support risk assessment is the Agency-wide research initiative process. While the Panel did not review the specific initiatives planned for FY'86 and FY'87, the Panel believes that the research initiative process can promote needed risk assessment research. As examples,

- Improvements in the exposure assessment methodology used in risk assessment need to be more directly coupled with present attempts to improve exposure monitoring procedures and data bases. Initiatives should be encouraged to improve interactions between ORD and program offices addressing both single and multimedia exposure issues.
- Identification of the risks associated with biotechnology deserves emphasis with a view to the development of risk assessment methodologies with associated data collection and testing protocols for health and environmental effects.

The Panel believes that an important priority is to increase the emphasis on peer-reviewed publication of EPA's risk assessment research projects. This will serve to (1) improve communication within the larger scientific community and (2) promote a higher quality of research. EPA's research on risk assessment methodology should be distinct from EPA policy on risk management. Therefore, it should be possible to publish risk assessment research results quickly without extensive internal Agency review.

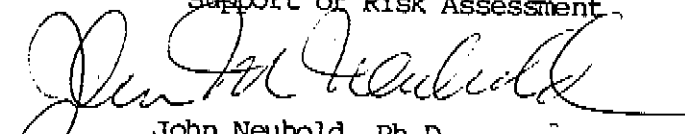
Because of the large amount of information, the Panel heard only brief summaries of selected projects. We could not evaluate the projects in detail. The Panel encourages further peer-review of these projects as a part of the risk assessment research process.

Critically important components of the Agency's research program on risk assessment should be given a long-term commitment, so as to place them on a stable funding basis. For example, the Panel believes that the Agency's project on risk assessment of complex pollutant mixtures has previously attracted sustained financial support. Other projects deserve such commitments.

Sincerely,



D. Warner North, Ph.D.  
Chair, Panel on Research in  
Support of Risk Assessment



John Neuhold, Ph.D.  
Chair, Subcommittee on Strategic  
and Long-Term Research Planning

cc: A. James Barnes [A-101]  
Bernard D. Goldstein [RD-672]