

September 30, 1997

EPA-SAB-EPEC-ADV-97-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Subject: Advisory on the Need to Develop Ecological Risk Management
Guidelines

Dear Ms. Browner:

The Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board met on July 22, 1997 in part to discuss with Agency staff approaches and key issues for future Agency guidelines on ecological risk management. Background materials provided to the Committee included the Agency document entitled *Priorities for Ecological Protection: An Initial List and Discussion Document for EPA* (hereafter referred to as the discussion document), prepared under the leadership of the Office of Research and Development's National Center for Environmental Assessment. In addition, the Committee received an oral briefing from Agency staff at the July meeting on preliminary efforts within the Agency to define the format and scope of possible ecological risk management guidelines. The Committee's advice on how to move forward in developing ecological risk management guidance for the Agency, contained in this SAB Advisory, was requested by Acting Assistant Administrator for Research and Development Henry Longest.

We appreciate the opportunity to provide comments on the subject of guidance on ecological risk assessment for risk managers. Based on the briefing provided at the EPEC meeting, it was apparent that the discussion document resulted from the initiative of a small group of individuals in different parts of the Agency who saw the need for such a document and made it happen. We wish to commend them for their initiative. Clearly, the topic of ecological risk management guidelines is very timely and deserves additional attention by the Agency. There is growing interest in the academic and private sector communities in establishing a dialogue on the subject. For example, the Society of Environmental Toxicology and Chemistry (SETAC) held a Pellston Workshop in June devoted to the subject of ecological risk management and the development of guidelines for risk managers. The Committee also noted that the EPA Office of Research and Development's Ecological Research Strategy, reviewed by the Committee on July 21, 1997, identified Ecosystem Risk Management as a Core

Research Area for the Agency. The Committee encourages the Agency to think more broadly about ecological entities to be protected, to include guidance for risk managers on the entire risk assessment process. This guidance should include discussion of how the risk characterization, including quantitative risk measures, can and should be used in making risk management decisions.

The Committee's response to the specific questions posed in the Charge to the Committee are provided below.

Charge Question 1: To what extent would the attached document (*Priorities for Ecological Protection: An Initial List and Discussion Document for EPA*) serve as a basis for guidance to risk management concerning what to protect? To what extent is it a basis for the process of setting goals during the planning stage of an ecological risk assessment? What additional endpoints, if any, would you recommend be included?

As a general summary, the discussion document is a good starting point for laying out first principles for selecting ecological entities to be protected and goals to be set. The document should help to increase the focus by risk managers on the Problem Formulation stage of the risk assessment process, which is often mistakenly slighted. It is during this part of the risk assessment that the entities to be protected are selected and upon which the remainder of the risk assessment is devoted. Carefully selecting the entities to be protected with the full support of the stakeholders is critical to the entire process.

The discussion document provides basic information on the process and criteria for selecting resources to be protected. The Committee is somewhat concerned, however, that the list of "eight ecological entities that are of wide spread concern" is too narrow to cover all ecosystems. The Committee discussed two possible options for providing guidance on ecological entities that should be considered in risk management decisions: the first option would be to define a list of entities that would serve as a minimum set that must be considered, and the second option would be to provide an expanded, comprehensive list of entities that would subsequently be narrowed for a particular decision based upon interaction and discussion among risk managers, risk assessors, and stakeholders. The Committee favors the second approach as the most likely to ensure that sufficient consideration is given to the appropriate entities. We suggest, therefore, that Table 4-1 be characterized as examples of entities to be protected and that it be expanded to include other areas, such as terrestrial ecosystems and managed ecosystems (crops, forests, etc.). In addition, a nested hierarchical list of entities and attributes might be developed such that a risk manager would be led through a series of questions that would ensure that sufficient thought and depth had gone into the selection process.

Relative to endpoint selection, the Committee suggests that in the future, as the list of ecological entities is expanded, the Agency might provide an additional set of tables with examples of assessment endpoints that could be developed for each entity. Subsequently, this list of assessment endpoints would serve as the basis for the risk assessors to select measurement endpoints. In order to avoid overwhelming risk managers with technical material, the revised discussion document might be thought of as the “primer,” with additional detail provided in supporting documents.

Charge Question 2: From the SAB’s viewpoint, to what extent does this document deal with the most important risk management issues during the planning and problem formulation stages?

The most critical portion of the Problem Formulation stage of ecological risk assessment is determining the entity or entities to be protected. The risk manager’s role at this stage is to help ensure that the Conceptual Model and Problem Formulation are framed in such a way that appropriate data are collected to provide a scientific basis that helps inform risk management decisions. The discussion document provides information on entity selection, but falls short of putting that guidance into the context of problem formulation and conceptual model development. We suggest that future documents include explicit discussion of how the selected entities are used in the problem formulation process.

In summary, the Committee compliments the Agency on the preparation of this initial document on ecological risk management and we urge the Agency to develop additional guidance for Agency risk managers, not only for the Problem Formulation stage of the risk assessment, but for the other stages as well. We would welcome the opportunity to continue this dialogue with the Agency as additional work is conducted on ecological risk management guidelines, and we look forward to a response to this letter from Assistant Administrator Longest.

Sincerely,

/signed/

Dr. Genevieve M. Matanoski, Chair
Executive Committee

/signed/

Dr. Mark Harwell, Chair
Ecological Processes and
Effects Committee

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