



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

December 17, 1984

Honorable William D. Ruckelshaus  
Administrator  
U.S. Environmental Protection Agency  
401 M Street, SW  
Washington, D.C. 20460

OFFICE OF  
THE ADMINISTRATOR

Dear Mr. Ruckelshaus:

The Environmental Protection Agency, in the implementation of its authorizing statutes, utilizes a number of modeling techniques to develop and enforce regulations and standards for various pollution sources. EPA utilizes models for at least three major predictive purposes. These include 1) as a supplement to, and sometimes substitute for, direct measurements; 2) to clarify environmental mechanisms and processes; and 3) as a tool for the development of policy guidance. Examples of the application of modeling by the Agency include the projection of exposures from land-based incinerators of liquid hazardous wastes and the determination of industrial source compliance with the National Ambient Air Quality Standards.

The widespread use of models by EPA, the states and the regulated community has major economic implications. More attention should be directed to the evaluation of the uncertainty and confidence limits to be applied to model results. It is also important to identify the relative fraction of the uncertainty that can be attributed to the various subcomponents of large, complex models. Without explicit identification of the assumptions and limitations of the submodels, it is impossible for one to judge whether or not a large model is consistent overall.

From time to time the Science Advisory Board (SAB) is asked to review models developed or used by the Agency. Many of these models have not been adequately tested for their reliability. Nor has the proper mix between monitoring and modeling been examined systematically. All models adopt simplifying assumptions and are therefore incomplete. A model validation effort should center around defining the extent of these limitations.

Validation of these pivotal procedures is a priority issue for EPA's research agenda. In view of this situation, the SAB makes the following recommendations:

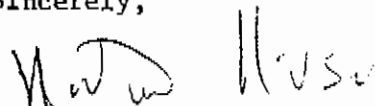
- o that EPA initiate a systematic effort at model validation. Given the Agency's increasing reliance upon exposure assessment in making risk assessment and risk management decisions, the SAB recommends that the Agency focus its efforts initially on the validation of exposure models.
- o that such an exposure model validation effort address the appropriate mix between monitoring and modeling.
- o that EPA seek to determine the relative utility of exposure modeling approaches for several biological media and systems that are of regulatory priority.
- o that EPA prepare an analytical rationale for this effort in the form of a case study that would discuss the approaches to be taken and milestones by which to measure the degree of success.
- o that the Agency seek SAB review of the model validation effort during the life of the project.

A first step toward implementation of this initiative would be to submit for SAB review a specific model, now in use or about to be introduced, so that its efficacy may be independently evaluated, including whatever progress EPA itself has made in validating it and exploring its applicability to other situations.

The Board fully recognizes that such an undertaking will require ample resources. By not taking a leadership position on the need to validate models, however, the Agency takes an even larger risk that many of its current procedures for assessing risk will soon be rendered obsolete. The SAB is concerned that this is already happening as current models are utilized for purposes for which they were not designed and for which there is insufficient scientific justification. The continuation and extension of this practice will cause further strains upon the Agency's scientific credibility.

I would like to discuss these SAB observations and recommendations with you and your successor at a mutually convenient time.

Sincerely,



Norton Nelson, Chairman  
Executive Committee  
Science Advisory Board

cc: Alvin Alm