



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

September 23, 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:

During the past four years the Environmental Health Committee of EPA's Science Advisory Board has recommended that the Agency analyze data on the pharmacokinetics of hazardous or potentially hazardous compounds. These requests have been made in the context of our review of individual assessment documents. Pharmacokinetics describes the absorption, distribution, metabolism and elimination of a substance by the body. Knowledge of pharmacokinetics is important since it can illuminate scientific issues by:

- Improving EPA's ability to understand different scenarios, such as acute high-level versus chronic low-level exposures to a substance.
- Enhancing the Agency's understanding of toxicity data in such aspects as bioaccumulation and organ-specificity.
- Influencing the consideration of whether to increase or decrease the quantitative estimate of risk for a substance (or the uncertainty in the estimate).

The Committee realizes that appropriate modification of a risk estimate by using pharmacokinetic information is a relatively new procedure for the Agency. Therefore, we suggest that EPA hold a public workshop or conference on this general topic to suggest procedures and/or draft guidance in this area. There are several significant advantages to holding such a workshop. A workshop presents:

- A forum for a more thorough and less hurried discussion of a number of significant scientific issues than would otherwise be available through the preparation and review of individual health assessment documents.

- A mechanism for building consensus within the scientific community regarding the Agency's risk assessment procedures.
- An opportunity for EPA to take a leadership position to influence both the research agenda for pharmacokinetic data and application of these data to risk assessment.

We have discussed the idea of holding a public workshop with Agency staff in the Office of Research and Development and the Office of Toxic Substances. They have indicated their support for the idea. The Science Advisory Board would be pleased to participate in such a workshop.

Sincerely,

Richard A. Griesemer

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