

December 8, 1995

EPA-SAB-EC-COM-96-001

The Honorable Carol Browner  
Administrator  
United States Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

Subject: Science Advisory Board Commentary on Hazard Identification

Dear Ms. Browner:

Recently, different committees of the SAB have provided advice to Agency programs on the hazard identification step of the risk assessment process that has been interpreted as being contradictory. Specifically, during their May 4 & 5, 1995 meeting, the Clean Air Scientific Advisory Committee (CASAC) noted that consideration of existing dose-response information about particulate loading should have been considered in the hazard evaluation of diesel emissions (EPA-SAB-CASAC-LTR-95-003). However, in their report on the Agency's Reproductive Toxicity Risk Assessment Guidelines (EPA-SAB-EHC-95-014), the Environmental Health Committee (EHC) expressed concern over the Agency's proposal to consider dose-response information during the hazard identification phase of risk assessment. The EHC comments were interpreted by some in the Agency as contradictory to what the CASAC was advising and to what the EHC had advised in an earlier report on the Agency's Developmental Toxicity Risk Assessment Guidelines (EPA-SAB-EHC-90-013).

In an attempt to clarify this situation, the Executive Committee has generated this commentary, using input from selected members of both CASAC and EHC. We want to clarify our thinking on this important issue in order to assist Agency scientists as they prepare to address the same issue in the Cancer Risk Assessment Guidelines that will be coming to the SAB for review later this fiscal year.

Commentary:

The National Academy of Sciences (NAS) risk assessment framework, described in the 1983 "Decision Making in the Federal Government: Managing the Process", has proven a useful and durable tool for assessing risk. It identifies easily understandable and recognizable steps for assessing risk and using the results for decision-making. In 1994, the National Academy of Sciences report, "Science and Judgment in Risk Assessment", recommended that EPA and others should broaden the types of information considered in the hazard identification phase of risk assessment. The SAB supports EPA's intent to expand the hazard identification and evaluation phase to include additional data. However, we recommend that the phases of the hazard identification process remain clearly discernable rather than simply being combined into an overall hazard characterization. Specifically, assessment of hazard should include a weight of evidence

evaluation of available experimental and epidemiological data.

The hazard identification should continue to be essentially qualitative in nature and should focus on the following where data are available: overall consistency of data, nature of the effects observed, relevance of the effect(s) to human health, mechanisms of action if known, pattern of dose-response relationships in the studies reviewed, and pharmacokinetic data where appropriate (especially in terms of qualitative differences in metabolic pathways between species). In contrast, the dose-response analysis step evaluates in quantitative terms the relationship between dose or exposure and severity or probability of effect in humans.

The SAB emphasizes the importance of conducting a hazard identification in cases in which data are not available to carry out the dose-response analysis and further steps of the risk assessment process. This approach is preventive in nature and gives impetus for follow-up by the research community and the Agency.

In conclusion, expanding the hazard identification step to include more information while retaining the step-wise approach laid out in 1983 provides for a more in-depth initial analysis of potential risk that is consistent with prevention and has the significant benefits of promoting consistency and clarity in the risk assessment process.

Closing:

We appreciate the opportunity to clarify the thinking of the Board on this matter and look forward to your response.

Sincerely,

Dr. Genevieve Matanoski, M.D., Chair  
Science Advisory Board