

August 3, 1995

EPA-SAB-CASAC-LTR-95-003

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

Subject: Review of the Diesel Health Assessment Document

A Panel of the Clean Air Scientific Advisory Committee (CASAC) met on May 4-5, 1995 to review the scientific and technical adequacy of the Agency's "Health Assessment Document for Diesel Emissions." Specifically, the Agency asked us the following questions: 1) Does the document accurately represent the key literature on diesel emissions? 2) Are the cancer and non-cancer hazard identification and dose-response assessments scientifically appropriate? In particular: a) Is the application of dosimetry modeling scientifically sound? b) Are the modes of action appropriately identified and applied to the health assessment? c) Are the qualitative and quantitative cancer risk estimates scientifically appropriate? d) Is the diesel reference concentration scientifically appropriate? and, 3) Is it possible to improve the diesel risk characterization in the document, given the inadequate exposure information to compare to the quantitative health assessment?

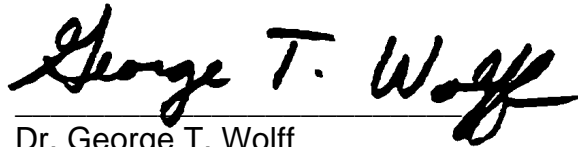
It was the consensus of the Panel that the present document is not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines. It is outdated and needs to be substantially revised and re-reviewed before the CASAC can come to closure. The Panel members provided the Agency with extensive comments on the document at the meeting and subsequently in writing.

Because of the rapid rate of change of relevant knowledge, the document is considerably out of date. A number of important new studies have not been included or adequately considered, and the Panel felt that their inclusion would change the focus and conclusions of the report. For example, EPA's quantitative risk assessment for lung cancer is based on animal carcinogenicity data for only one species, the rat, with no comparable response in two other species. The cancer-causing mechanism in the rat may be unique to the rat and does not appear to occur in other species including humans. The mechanism in rats is apparently related to particulate overload followed by a sequence of events beginning with inflammation and ending in tumorigenesis.

These events are conditional upon particle overload which also occurs in rats exposed to high concentrations of inert dusts as well. Consequently, it appears that these studies are not relevant for human risk assessments.

We appreciate the opportunity to assist the Agency, and we look forward to receiving the revised version when it is available.

Sincerely,

A handwritten signature in black ink that reads "George T. Wolff". The signature is written in a cursive style with a horizontal line underneath it.

Dr. George T. Wolff
Chair, Clean Air Scientific Advisory Committee
Science Advisory Board

August 3, 1995

Date