



**EPA**

**U.S. Environmental  
Protection Agency**

**Washington, DC  
EPA-SAB-CASAC-90-002**

---

**Report of the Clean Air Scientific  
Advisory Committee (CASAC)**

**Review of the OAQPS Lead Staff Paper  
and the ECAO Air Quality Criteria  
Document Supplement**



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

OFFICE OF  
THE ADMINISTRATOR

January 3, 1990

Honorable William K. Reilly  
Administrator  
U.S. Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

RE: National Ambient Air  
Quality Standards for Lead

Dear Mr. Reilly:

I am pleased to transmit the advice of the Clean Air Scientific Advisory Committee (CASAC) concerning the National Ambient Air Quality Standards (NAAQS) for Lead. The CASAC has reviewed and offered comments directly to EPA Staff on the EPA Air Criteria Document update, "Supplement to the 1986 EPA Air Quality Criteria for Lead - Volume I Addendum (Pages A1 - A67)", and the Office of Air Quality Planning and Standards (OAQPS) staff position paper "Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information", both dated March 1989.

The Committee previously reached closure on the 1986 Air Quality Criteria Document and Criteria Document Supplement. At a meeting held on April 27, 1989, CASAC reviewed and was prepared to close on the 1989 Criteria Document Addendum and the 1989 Staff Position Paper, but withheld closure pending receipt and consideration of additional public comments. The public comment period, scheduled to close 30 days following the CASAC meeting, was extended through June 12, 1989, providing the interested public further time to prepare comments. The additional comments received as a result of the extended comment period were provided to the Committee and taken into consideration before reaching closure. The Committee concludes that these EPA documents, along with the 1986 documents previously closed upon, provide a scientifically balanced and defensible summary of our current knowledge of the

effects of this pollutant, providing an adequate scientific basis for EPA to retain or revise primary and secondary NAAQS for airborne lead.

As part of this review process, the Committee considered and approved the CASAC Exposure Subcommittee review of the August 1988 EPA document "Review of the National Ambient Air Quality Standards for Lead: Exposure Analysis Methodology and Validation". That approval is formally contained in the CASAC report transmitted to you in April 1989 (EPA-SAB-CASAC-89-018, April 1989).

In November 1988, the CASAC formed an ad hoc Joint Study Group with the Science Advisory Board (SAB). The broad charge to this Study Group included assessment of the weight of evidence classification of lead and lead compounds as carcinogens; review of lead-related health effects and exposure issues which cut across EPA organizational lines; and an assessment of how the scientific information concerning lead is applied to standard setting and other regulatory decisions in the Agency. The report of that Joint Study Group, based on their March 30, 1989 and April 28, 1989 meetings, is contained in their report (EPA-SAB-EC-90-001, December 1989), transmitted to you separately.

A key point of the Joint Study Group Report is the contrasting nature of the data base for central nervous system versus carcinogenic effects. The carcinogenic risk assessment is based primarily on induction of kidney tumors in rodents administered large quantities of lead. Use of these data for human risk assessment involves two extrapolations: from rodents to people, and from high doses to the low doses encountered in ambient exposures of lead. In contrast, central nervous system effects are observed directly in people and at exposures at or near the levels of exposure relevant to setting the standard. Thus, and unless, more quantifiable and relevant scientific evidence is available on the carcinogenicity of lead, the Committee feels it appropriate to give primary consideration to nervous system effects in setting the national ambient air quality standard for lead.

During the course of the CASAC meeting several recommendations were made to the EPA Staff as to actions that can be taken that will provide an improved basis for setting the NAAQS for lead. These include calculation of the distribution of blood lead levels estimated to result from achieving an air lead concentration of

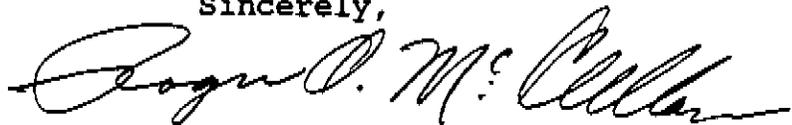
0.25 ug/m<sup>3</sup>. In addition, it was suggested that it would be appropriate to evaluate the estimated distribution of effects on childrens intelligence at a given level of lead exposure.

While the Committee is willing to further advise you on the lead standard, we see no need, in view of the extensive comments provided, to review any proposed changes prior to their publication in the Federal Register. The public comment period following publication will provide sufficient opportunity for the Committee to provide any additional comment or review, if needed.

The attached report contains the detailed analysis and recommendations of the CASAC concerning its closure on the Criteria Document Addendum and the EPA Staff Position Paper for airborne lead. In considering the CASAC's recommendations for the lead NAAQS it is important to recognize that air is just one source of exposure to lead; reducing the total population risk from lead will require a concerted effort to reduce lead intake from all sources.

We appreciate the opportunity to provide advice on this important issue and look forward to your response to our recommendations.

Sincerely,



Roger O. McClellan, D.V.M.  
Chairman, Clean Air Scientific  
Advisory Committee

## ABSTRACT

This is the report of the EPA's Clean Air Scientific Advisory Committee (CASAC) on its review of the Agency's draft documents: "Supplement to the 1986 Air Quality Criteria for Lead - Volume I Addendum (Pages A1 - A67)", and "Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information", both dated March 1989. These documents were reviewed in public session on April 27, 1989, with the Committee reaching the conclusion that the documents provide an adequate scientific and technical basis for EPA to retain or revise primary and secondary national ambient air quality standards for lead.

Key Words:           Lead; National Ambient Air Quality Standards; NAAQS;  
Air Pollution

## NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency; and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or other agencies in the Federal government. Mention of trade names or commercial products does not constitute a recommendation for use.

U.S. Environmental Protection Agency  
Science Advisory Board

Clean Air Scientific Advisory Committee Lead Review Committee

Chairman

Dr. Roger O. McClellan\*, Chemical Industry Institute of Toxicology,  
Research Triangle Park, North Carolina

Co-Chairman

Dr. Arthur Upton, New York University Medical Center, Department  
of Environmental Medicine, New York, New York

Members

Dr. Gary Carlson, Department of Pharmacology and Toxicology,  
School of Pharmacy, Purdue University, West Lafayette,  
Indiana

Dr. J. Julian Chisolm, Jr., Johns Hopkins School of Medicine,  
Francis Scott Key Medical Center, Baltimore, Maryland

Dr. Robert Frank, The Johns Hopkins School of Hygiene and Public  
Health, Baltimore, Maryland

Dr. Paul B. Hammond, Department of Environmental Health,  
University of Cincinnati Medical Center, Kettering  
Laboratory, Cincinnati, Ohio

Dr. Timothy Larson\*, Environmental Engineering and Science  
Program, Department of Civil Engineering, University of  
Washington, Seattle, Washington

Dr. Ian von Lindern, President, Terragraphics Environmental  
Engineering, Moscow, Idaho

Dr. Morton Lippmann, Institute of Environmental Medicine, New  
York University Medical Center, Tuxedo, New York

Dr. Kathryn R. Mahaffey, National Institute of Environmental  
Health Sciences, University of Cincinnati Medical  
Center, Cincinnati, Ohio

Dr. Paul Mushak, Consultant and Adjunct Professor, University  
of North Carolina, Chapel Hill, North Carolina

Dr. Gilbert S. Omenn\*, School of Public Health and Community  
Medicine, University of Washington, Seattle, Washington

- Dr. Michael B. Rabinowitz, Marine Biological Laboratory, Wood's Hole, Massachusetts
- Dr. Marc B. Schenker\*, Occupational and Environmental Health Unit, University of California, Davis, California
- Dr. Ellen Silbergeld, Environmental Defense Fund, Washington, DC
- Dr. Mark J. Utell\*, Pulmonary Disease Unit, University of Rochester School of Medicine, Rochester, New York
- Dr. Bernard Weiss, Division of Toxicology, Department of EHSC, School of Medicine, University of Rochester, Rochester, New York
- Dr. Jerome J. Wesolowski\*, Air and Industrial Hygiene Laboratory, California Department of Health, Berkeley, California
- Dr. George T. Wolff\*, General Motors Research Laboratories, Environmental Science Department, Warren, Michigan

\* Statutory CASAC Members

Science Advisory Board Staff

- Mr. A. Robert Flaak, Designated Federal Official, Science Advisory Board (A-101F), U.S. Environmental Protection Agency, Washington, D.C. 20460
- Ms. Carolyn Osborne, Staff Secretary, Science Advisory Board (A-101F), U.S. Environmental Protection Agency, Washington, DC 20460

REPORT OF THE CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE  
ON ITS REVIEW OF  
THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR LEAD

-----

CASAC CLOSURE ON THE 1989 AIR QUALITY CRITERIA  
DOCUMENT ADDENDUM AND 1989 STAFF POSITION PAPER

At a public meeting held on April 27, 1989, CASAC reviewed the EPA Air Criteria Document update, Supplement to the 1986 EPA Air Quality Criteria for Lead - Volume I Addendum (Pages A1 - A67), and the Office of Air Quality Planning and Standards (OAQPS) staff position paper Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information, both dated March 1989. The Committee concluded that these documents, along with the documents previously closed upon, provide a scientifically balanced and defensible summary of the current basis of our knowledge of the effects of this pollutant, providing an adequate scientific basis for EPA to retain or revise primary and secondary NAAQS for airborne lead.

In discussing blood lead levels used to assess alternative standards, it is the consensus of CASAC that blood lead levels above 10 ug/dl clearly warrant avoidance, especially for development of adverse health effects in sensitive populations. The value of 10 ug/dl refers to the maximum blood-lead level permissible for all members of these sensitive groups, and not mean or median values. The Committee concluded that the Agency should seek to establish an air quality standard which minimizes the number of children with blood lead levels above a target value of 10 ug/dl. In reaching this conclusion, the Committee recognizes that there is no discernible threshold for several lead effects and that biological changes can occur at lower levels. In setting a target value for blood lead (matched ultimately to air lead level) the Committee emphasized the importance of always being mindful that blood lead levels and health outcome measures are best characterized as a distribution of values about mean or median values. The importance of considering the distribution of values about the mean or median is apparent from consideration of the influence of lead exposure on I.Q. A seemingly modest decrease in the mean or median value for I.Q. may result in significant changes

at the outer limits of the distribution with both a reduction in the number of bright children (I.Q. > 125) and an increase in the number of children with I.Q. < 80.

In setting a blood lead target value (and the associated air lead concentration) it is important to recognize that lead may enter the body by both the inhalation and ingestion routes and that oral intake may make significant contribution to a child's total exposure to lead. For example, lead in food, water, soil and paint are all contributors to total lead intake. Achieving a target blood level will require an integrated approach with appropriate standards for all routes of exposure, not just lead in air. The Committee emphasized that assessment of risks of adverse health effects is based on lead blood levels or body burden estimates, and only indirectly on the air lead concentrations.

Lead is a toxic poison with no known beneficial function in the human body. An individual exposed is at risk to a wide range of effects in numerous organ systems and tissues. The EPA staff have correctly identified the fetus and young children as particularly sensitive population groups due to physiological sensitivity during fetal development when the central nervous system is undergoing its most pronounced growth, and due to early developmental impairment associated with fetal exposure. In addition, the Committee concurs with the staff's assessment of risks associated with increased blood pressure related to lead in adult populations. As discussed below, quantitative exposure analyses in the Staff Position Paper were not done for populations of pregnant women and their fetuses exposed under alternative standards.

The Committee finds that the methodologies applied in the staff paper case study analysis on young children and adult men provide an appropriate tool to evaluate relative protection of alternative lead NAAQS. Although these analyses are useful in comparing standards, they should not be used to provide estimates of absolute numbers of individuals at risk. In addition, populations not evaluated quantitatively because of the lack of valid data (e.g., pregnant women/fetuses) must be considered in determining an appropriate margin of safety for the standard. The Committee recognizes, as noted by the CASAC Exposure Subcommittee, that valid modeling predictions are not possible at this time due to a lack of relevant data.

The EPA Staff recommended in the Staff Position Paper that the lead NAAQS be expressed as a monthly standard in the range of 0.5 to 1.5 ug/m<sup>3</sup> not to be exceeded more than once in three years. The Committee concurs with the EPA Staff recommendation to express the lead NAAQS as a monthly standard not to be exceeded more than once in three years. The Committee strongly recommends that in selecting the level of the standard you take into account, the significance and persistence of the effects associated with lead as well as those sensitive population groups for which valid quantitative exposure/risk estimates could not be made at this time. The Committee believes you should consider a revised standard with a wide margin of safety, because of the risk posed by lead exposures, particularly to the very young whose developing nervous system may be compromised by even low level exposures. At the upper level of the staff paper range (1.0-1.5 ug/m<sup>3</sup>), there is relatively little, if any, margin of safety. Therefore, the Committee recommends that in reaching a decision on the level of the standard, greater consideration be given to air lead values below 1.0 ug/m<sup>3</sup>. To provide perspective in setting the NAAQS for lead it would be appropriate to have the EPA Staff compute the distribution of blood-lead levels resulting from a monthly standard of 0.25 ug/m<sup>3</sup> for comparison with the values already computed for higher levels. In setting the NAAQS for lead it is important to recognize that airborne lead serves not only as a source of inhalation exposures, but that lead in air deposits on soil and plants becoming a potential source for intake into the body.

The CASAC agrees with the EPA staff recommendation for more frequent sampling near point sources, but has reservations about continued reliance on the hi-volume sampler for measuring airborne lead. While the hi-volume sampler may be a reasonable indicator for purposes of determining compliance with a monthly lead standard, the Committee believes that more refined instruments for characterizing airborne lead exposures are needed. The Committee recommends that the Agency develop or validate lead instrumentation that is capable of measuring both direct and indirect airborne lead exposures so more refined air quality data will be available for the next review. Finally, the Committee concurs with the staff recommendation that the use of PM<sub>10</sub> samplers be permitted in areas where they produce similar results as the hi-volume sampler.

Given that lead has no biologic value, the Committee strongly recommends that the Agency actively pursue a public health goal of

minimizing the lead content of blood to the extent possible, recognizing that as a naturally occurring element, lead will be present at background levels. The air quality standard is an important component of a strategy for achieving the goal, however, the NAAQS for lead by itself is not sufficient to achieve the goal. Instead, a concerted effort must be made to further reduce lead exposures through all media of concern.