



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

December 15, 1988

OFFICE OF
THE ADMINISTRATOR

The Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection
Agency
401 M Street, SW
Washington, D.C. 20460

RE: CASAC Advice on Acid Aerosols

Dear Mr. Thomas:

I am pleased to transmit via this letter the advice of the Clean Air Scientific Advisory Committee (CASAC) concerning the potential health effects of acid aerosols. The current activity is traceable to concerns of CASAC that developed sometime ago during the Committee's consideration of the Air Quality Criteria Document on Particulates and Sulfur Oxides. To facilitate consideration of the potential health effects of acidic aerosols by the Agency, the CASAC recommended that the EPA staff prepare an "Acid Aerosols Issue Paper". A CASAC Subcommittee on Acid Aerosols was created to review the Issue Paper and prepare a report on acid aerosol research needs. Enclosed are copies of the Subcommittee's report to CASAC on the Issue Paper, and its report on acid aerosol research needs.

In addition to consideration by the Subcommittee, the full CASAC at a meeting on October 6, 1988 reviewed the Issue Paper, the Subcommittee's research needs report, and deliberated on the advice to be provided to you.

In the opinion of the CASAC, the issue of the potential health effects of acid aerosols is a matter of substantial concern that clearly warrants additional attention by the Agency. This is particularly true for the particle phase of the aerosol. Although the Committee also recognized that the aerosol vapor phase may also be implicated in adverse health effects, the health and monitoring data available at this time are insufficient to warrant more than recommendations for further research.

Information from animal toxicological experiments and controlled exposure of human subjects is developing on the health effects of acid particles in a range of concentrations approaching that observed in the ambient environment. Preliminary evidence from epidemiological investigations also implicates acid particles as a factor contributing to human health effects. Additional research of this type is underway and should receive continued support since it is urgently needed to clarify the effects of acid particles at ambient exposure concentrations.

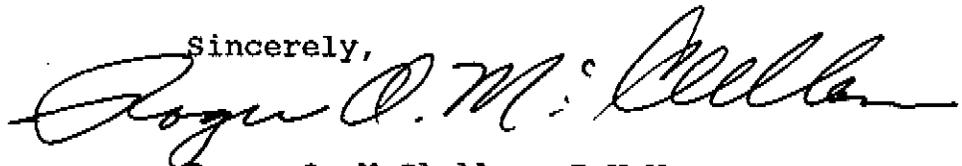
Limited data are available on the concentrations and characteristics of acid particles in various parts of the United States. These data have largely been gathered using research procedures rather than standardized monitoring methods and thus it is not possible at this time to adequately characterize the exposure of the U.S. population to acid particles. To remedy this deficiency, the CASAC urges the Agency to develop and deploy for use a standardized method for monitoring air concentrations of acidic particles. The Committee recognized that the most useful method would be one which speciated all acids present. Since this is impractical for monitoring purposes at this time, the Committee believed that monitoring for total particle acidity would be a reasonable compromise. A final decision on the measurement method should await the method workshop recommended by the CASAC in its report on Acid Aerosol Research Needs.

The CASAC strongly recommends that the Agency initiate in an expeditious manner the preparation of a detailed substantive analysis of the available and emerging scientific information on acid particles, and at the appropriate time prepare an associated Staff Position Paper. This detailed substantive analysis, with the rigor used in preparation of a Criteria Document, should provide a factual basis for determining the degree which acid particles concentrations in ambient air will endanger public health. The Staff Position Paper should, among the various topics covered, address the issue of whether the potential health effects of acid particles warrant additional action to protect public health, either through use of one of the existing standards, such as the PM₁₀ standard for airborne particulates or by developing a separate, unique standard for acid particles. The process of preparing and reviewing these documents will introduce a degree of rigor that should help assure that the Administrator receives the best possible advice.

The CASAC specifically recommends proceeding on multiple fronts: (a) support of additional research on health effects, (b) development of a standardized measurement procedure, (c) collection of monitoring data across the United States, and (d) initiation of the preparation of the analytical documents described above. It is the Committee's opinion that this multifaceted approach with activities proceeding in parallel when possible, assures that this important public health issue will be dealt with in a timely manner. The Committee was strongly opposed to an alternative approach of only conducting additional research in the absence of action in the other areas.

The CASAC would appreciate receiving a response concerning the Agency's plans for dealing with the acid particle issue. Please do not hesitate to contact me if the CASAC can be of further assistance on this matter.

Sincerely,

A handwritten signature in cursive script, reading "Roger O. McClellan".

Roger O. McClellan, D.V.M.
Chairman

Enclosure

cc: Donald Barnes
Erich Bretthauer
Don Clay
Ray Loehr

United States
Environmental Protection
Agency

Office of the Administrator
Science Advisory Board
Washington, DC 20460

EPA-SAB/CASAC-89-009
December 1988



EPA

Report Of The Clean Air Scientific Advisory Committee (CASAC)

Acid Aerosol Health Effects

CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

ADVICE CONCERNING
ACID AEROSOL HEALTH EFFECTS

FINAL REPORT
DECEMBER 15, 1988

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
WASHINGTON, DC

ABSTRACT

Under Section 109 of the Clean Air Act, the U.S. Environmental Protection Agency (EPA) is required to periodically review national ambient air quality standards (NAAQS) and the criteria on which they are based. The Act also requires the Clean Air Scientific Advisory Committee (CASAC) to provide scientific advice on any additional knowledge that is required to evaluate existing, or setting new or revised NAAQS. To evaluate the health effects of the class of air pollutants known as acid aerosols, the Committee requested that EPA prepare an "Acid Aerosol Issue Paper". This Issue Paper was reviewed by the Acid Aerosol Subcommittee of CASAC in June 1988. In October 1988, the Issue Paper, and the Subcommittee's two reports (Acid Aerosol Research Needs, and Report on the Acid Aerosol Issue Paper) were reviewed by the CASAC. This report presents the conclusions and recommendations of the CASAC on the potential health effects of acid aerosols. Included as an enclosure, is the Acid Aerosol Subcommittee report to the CASAC (Science Advisory Board Report No. EPA-SAB/CASAC-89-001).

Key Words: acid aerosols, acid particles, NAAQS

U.S. Environmental Protection Agency

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 do not constitute a recommendation for use.

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD

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Executive Secretary

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401 M Street, SW, Washington, D.C. 20460

ENCLOSURE

CASAC Acid Aerosol Subcommittee
Report to the
Clean Air Scientific Advisory Committee

(Science Advisory Board Report No. EPA-SAB/CASAC-89-001)



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

October 6, 1988

OFFICE OF
THE ADMINISTRATOR

Dr. Roger McClellan, Chairman
Clean Air Scientific Advisory Committee
Science Advisory Board (A-101F)
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Dr. McClellan:

This letter transmits the conclusions of the CASAC Acid Aerosol Subcommittee concerning listing acid particles as a criteria pollutant. The Subcommittee met on June 14-15, 1988 in Washington, DC to review the draft "Acid Aerosols Issue Paper" (EPA/600/8-88/005A) prepared by EPA's Office of Research and Development.

The Subcommittee concensus, although not unanimous, was that CASAC recommend to the Administrator that he consider listing acid particles under Section 108 of the Clean Air Act. In the Subcommittee's view, the cumulative evidence provided by the available animal, controlled human exposure, and epidemiologic studies clearly suggests possible health effects associated with exposure to acid particles. The Subcommittee recognizes that the available data base is not complete but is concerned by the potential health risks resulting from exposures under typical ambient conditions. The Subcommittee concluded that the weight of the evidence from the disciplines of animal toxicology, controlled clinical studies, and epidemiology is sufficient at this time to recommend that the Administrator consider listing of acid particles as a criteria pollutant.

In summary, it should be noted that the majority vote was cast on the basis of the weight of the evidence from the three health related disciplines rather than on any single study. A more detailed discussion of the Subcommittee position is included in the attached report.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Utell".

Mark J. Utell, MD
Chairman
Acid Aerosol Subcommittee

ABSTRACT

Under Section 109 of the Clean Air Act, the U.S. Environmental Protection Agency (EPA) is required to periodically review national ambient air quality standards (NAAQS) and the criteria on which they are based. The Act also requires the Clean Air Scientific Advisory Committee (CASAC) to provide scientific advice on any additional knowledge that is required to evaluate existing, or setting new or revised NAAQS. To evaluate the health effects of the class of air pollutants known as acid aerosols, the Committee requested that EPA prepare an "Acid Aerosol Issue Paper". This Issue Paper was reviewed by the Acid Aerosol Subcommittee of CASAC in June 1988. This report presents the conclusions and recommendations of that Subcommittee as transmitted to the CASAC.

Key Words: acid aerosols, acid particles, NAAQS

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Subcommittee

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
Acid Aerosol Subcommittee

Recommendations on Listing Acid
Particles as a Criteria Pollutant

1.0 Background

Under section 109(d) of the Clean Air Act the EPA must periodically review the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based, and must revise such criteria and standards as appropriate. In the process of reviewing new scientific studies concerning health effects of particulate matter and sulfur oxides in 1986, it became apparent that researchers had identified acid aerosols as a constituent of the airborne mix of these pollutants that may be associated with observed health effects. As a result, the Clean Air Scientific Advisory Committee (CASAC) recommended that the Agency prepare an Acid Aerosols Issue Paper to evaluate the emerging literature concerning health effects directly associated with acid aerosols.

The Agency completed this draft Issue Paper in early 1988 and presented it to the CASAC Acid Aerosol Subcommittee on June 14-15, 1988. The Subcommittee faced three primary tasks. First, whether available scientific information provided sufficient and compelling evidence for a listing of acid particles as a prelude to development of a separate criteria pollutant, second, to assess the adequacy of the Issue Paper, and third, to identify and prioritize research needed to respond to the critical issues identified in the draft Issue Paper as well as any additional issues identified by the Subcommittee itself. The first and second issues are addressed in this report, the third is discussed in a separate research recommendations report (EPA-SAB/CASAC-89-002).

2.0 Options facing the Subcommittee

In addressing the listing issue, the Subcommittee considered the three options presented by EPA in the draft Issue Paper:

1) Recommend that the Administrator consider listing acid aerosols under Section 108 of the Act. This implies a judgment that the available health effects information is compelling enough to require additional protection beyond the current NAAQS. Within 12 months of a listing decision, EPA must issue air quality criteria and propose standards.

2) Recommend that the Administrator not consider listing acid aerosols under Section 108 of the Act. The available health effects information as well as any new research would be considered during the next review of the particulate matter standards.

3) Recommend that the Administrator defer judgment regarding action to list acid aerosols pending further research on the critical needs identified in Chapter 8 (Research Needs) of the draft Acid Aerosols Issue Paper.

In its discussion of research issues, the Subcommittee considered research needs identified by the Agency in the Issue Paper, research needs identified by the members of the Subcommittee, and presentations from the interested public at the June 14-15, 1988 meeting.

3.0 Major Research Findings that Support the Subcommittee Recommendations

The majority vote was based on the weight of evidence from research involving the three disciplines of animal toxicology, controlled clinical exposures, and epidemiologic studies. The key findings from recent toxicology research include: in chronic daily exposures of rabbits ($250 \mu\text{g}/\text{m}^3$ for 1-hr/day, 5 days/week for one year) persistent alterations of mucociliary and alveolar particle clearance, airway reactivity, airway secretory cell density and characteristics, and airway caliber changes were produced (Gearhart and Schlesinger, 1988). Such changes were similar to those produced by chronic exposure to cigarette smoke, suggesting that chronic bronchitis could result from more prolonged exposures. Furthermore, in single 3-hour and 5 days of 3-hour daily exposures to ultrafine acid coated zinc oxide particles with sulfuric acid concentrations in the range of $20\text{-}30 \mu\text{g}/\text{m}^3$, guinea pigs developed persistent changes in vital capacity, airway compliance, lung permeability, and carbon-monoxide diffusing capacity (Amdur and Chen, 1988). Similar results were obtained with $200 \mu\text{g}/\text{m}^3$ of ultrafine droplets of pure sulfuric acid. These findings suggest that primary and secondary sulfuric acid occurring as coatings on ultrafine fly ash particles may be considerably more toxic than secondary acidic aerosol which is found in the atmosphere in solution droplets.

Recent data from controlled clinical studies lends additional support for a relationship between exposure to near ambient levels of acid aerosols and adverse respiratory effects. In 1983, Koenig et al., (1983) identified allergic adolescent asthmatics as a subgroup responsive to inhalation of $100 \mu\text{g}/\text{m}^3$ sulfuric acid aerosols (30 minutes at rest followed by 10 minutes of exercise). These researchers have extended further their observation in allergic adolescent asthmatics linking exposure to near ambient levels of sulfuric acid at $68 \mu\text{g}/\text{m}^3$ with significant alterations in lung function (Koenig et al., 1988). The FEV_1 decreased 6% after inhalation of sulfuric acid using the previously described exposure protocol vs 1% decrease after breathing air. Furthermore, the most recent findings from Bauer et al. (1988) support Koenig's findings in that adult allergic asthmatics showed greater decrements in FEV_1 breathing $75 \mu\text{g}/\text{m}^3$ sulfuric acid vs. NaCl (control) for 2 hours in an environmental chamber. Based on our understanding of the current

data base, extrapolation to longer exposures coupled with more rigorous exercise could serve to intensify the response.

Data linking acid aerosols with respiratory health effects emerges from the ongoing field studies. Speizer (1988) showed that bronchitis in 10-12 year old children in four U.S. cities varied from about 3-11% from standardized questionnaire responses in direct relation to annual average concentration of aerosol H^+ , with the highest prevalence in the community with the highest annual average H^+ concentration which was 1.8 ug/m^3 (expressed as sulfuric acid equivalents). Similar associations were seen for other respiratory symptom responses in the same population. While the prevalence data were for the 1981 school year and the concentration data were for 1985-1988, it has been established in other studies from the six cities group that the bronchitis prevalence in these cities were in similar proportion in this population in other years, and that there was little variation in annual average pollution levels during these years. There were occasional exceedences of the current NAAQS for PM and SO_2 in some of these communities during some of the years covered by these studies, nevertheless, the Subcommittee is concerned that the current NAAQS may not provide adequate protection against such health effects.

4.0 Review of Issue Paper

The draft Issue Paper was generally considered to be well prepared and comprehensive. Most members of the Subcommittee provided detailed written comments concerning the draft to the Agency during and following the June 14-15, 1988 meeting. Extensive discussion occurred during the meeting which pointed out the need to address certain issues further. An example of such an issue is to define the pollutant indicator to regulate, its form, and measurement methodology.

5.0 Subcommittee Recommendations to CASAC

Following a careful review of the Issue Paper and extensive deliberations, members of the Subcommittee voted and reached the nearly unanimous conclusion¹ that the Clean Air Scientific Advisory Committee should recommend that the Administrator consider listing acid particles as a criteria pollutant. However, one Subcommittee member was in favor of recommending that the Administrator not consider listing acid particles, and one member was in favor of recommending that the Administrator defer such a decision until further research was completed. The minority positions are presented first.

¹ The Subcommittee vote was: 9 in favor of recommending that the Administrator consider listing, 1 in favor of recommending that the Administrator not consider listing, and 1 in favor of recommending that the Administrator defer judgment pending further research.

5.1 Recommendation to Defer Decision (Dr. Robert Phalen)

1) Although there is scientific evidence that airborne acidity at or near levels found in the environment is capable of harming respiratory tract tissues, I recommend that the decision to list acid aerosols as a NAAQS be deferred pending further research directed at resolving several basic issues. First, it is not at all clear just what the relevant air contaminant is. Airborne acidity can be in vapor forms and in particulate forms. In some cases, the acid vapor exceeds the particles in total mass. The full combination - that is the total acid present in all forms - is the logical agent to consider for listing because that is what is inhaled. This is also valid scientifically as many of us believe that an aerosol consists of a two-phase system of particles and a surrounding gas. However, the Subcommittee did not agree to include vapor phase acidity. Further research will very likely show that "total available hydrogen ion per unit volume of ambient air" is the entity that relates to adverse biological effects. Until this research is done our recommendation to list will possibly ignore a major fraction of the potentially hazardous agent and thus may under-protect exposed populations.

2) Next, the presently available human clinical exposure studies are for short periods - usually less than two hours. Because populations will be exposed for very prolonged periods additional studies are desperately needed. Longer exposures may show that effects increase upon longer exposure or alternatively that effects disappear upon longer exposure. Such studies are critical to defining whether peak levels of acidity or some integrated measure of acid exposure should be listed. Without this clarification substantial over-protection or under-protection could result.

3) Finally, we do not presently have enough animal toxicology data to identify the most sensitive sites in the body with respect to acid injury. One must have such information in order to project what human sub-populations are at greatest risk and what the expected risks are.

4) Certainly the acid aerosol issue should not be dropped. The available evidence indicates the real potential for airborne acidity contributing to adverse effects in human populations. However, until the above basic issues are better understood it is difficult to envision the establishing of a proper NAAQS.

5.2 Recommendation Not to List (Dr. George Wolff)

1) Health effects due to acid aerosols have been demonstrated in controlled exposures but only at concentrations which are much greater than an order of magnitude higher than typical ambient levels. Even the highest concentration ever reported in the ambient air is significantly lower than the

lowest documented concentration ever associated with a physiological response.

2) The assumption that the threshold dose for an adverse health effect is $100 \mu\text{g}/\text{m}^3\text{-hr}$ (i.e., $100 \mu\text{g}/\text{m}^3 \times 1 \text{ hour} = 10 \mu\text{g}/\text{m}^3 \times 10 \text{ hours}$) is not supported by any of the data. In fact, it is contrary to conventional wisdom because the body produces ammonia which will neutralize a certain amount of the acidity.

3) I question the accuracy of the ambient data, particularly the extreme values, since there is no standard procedure for measuring acid aerosols and the techniques used have not been subjected to rigorous quality assurance protocols.

5.3 Majority Conclusions - Recommendation to List²

Based on its assessment of the technical and scientific information presented in the Issue Paper, the Subcommittee reached a nearly unanimous conclusion that the Clean Air Scientific Advisory Committee should recommend that the Administrator consider listing acid particles as a criteria pollutant. In the Subcommittee's view, the cumulative evidence provided by the available animal, controlled human exposure, and epidemiologic studies clearly suggests possible health effects associated with exposure to acid particles. The Subcommittee recognizes that the available data base is not complete but is concerned by the potential health risks resulting from exposures under typical ambient conditions. The Subcommittee concluded that the weight of the evidence from the disciplines of animal toxicology, controlled clinical studies, and epidemiology is sufficient at this time to recommend that the Administrator consider listing of acid particles as a criteria pollutant.

In arriving at its recommendation, the Subcommittee took into account that research currently underway should begin to provide needed supplemental information in the next several years. To further augment these ongoing efforts, the Subcommittee has also identified key research needs that the Agency should begin to address immediately through a balanced and adequately funded research program. These are discussed in the separate report on acid aerosol research recommendations.

2 These nine members were: Dr. Mary Amdur, Dr. Doug Dockery, Dr. Robert Frank, Dr. Timothy Larson, Dr. Morton Lippmann, Dr. Gilbert Omenn, Dr. Marc Schenker, Dr. Jerome Wesolowski, and Dr. Mark Utell.

6.0 Literature Cited

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APPENDIX A

Roster of the CASAC Acid Aerosol Subcommittee

February 1988

U.S. Environmental Protection Agency
Science Advisory Board
Clean Air Scientific Advisory Committee

Acid Aerosol Subcommittee

Chairman

Dr. Mark Utell, Co-Director, Pulmonary Disease Unit, Professor of Medicine and Toxicology, University of Rochester Medical Center, Box 692, Rochester, NY 14642

Members

Dr. Mary Amdur, Senior Research Scientist, Energy Laboratory, MIT, Room 16-339, Cambridge, MA 02139

Dr. Doug Dockery, Harvard University, School of Public Health, Department of Environmental Science and Physiology, 665 Huntington Avenue, Boston, MA 02115

Dr. Robert Frank, Professor of Environmental Health Sciences, Johns Hopkins School of Hygiene and Public Health, 615 N. Wolfe Street, Baltimore, MD 21205

Dr. Timothy Larson, Environmental Engineering and Science Program, Department of Civil Engineering FX-10, University of Washington, Seattle, WA 98195

Dr. Morton Lippmann, Professor, Institute of Environmental Medicine, NYU Medical Center, Tuxedo, NY 10987

Dr. Gilbert Omenn, Professor and Dean, School of Public Health and Community Medicine SC-30, University of Washington, Seattle, WA 98195

Dr. Robert F. Phalen, Community and Environmental Medicine, College of Medicine, University of California-Irvine, Irvine, CA 92717

Dr. Marc Schenker, Director, Occupational and Environmental Health Unit, University of California, Davis, CA 95616

Dr. Jerry Wesolowski, Air and Industrial Hygiene Laboratory, California Department of Health, 2151 Berkeley Way, Berkeley, CA 94704

Dr. George Wolff, Senior Staff Research Scientist, General Motors Research Labs, Environmental Science Department, Warren, MI 48090

Executive Secretary

Mr. A. Robert Flaak, Environmental Scientist, Science Advisory Board (A-101F), U.S. Environmental Protection Agency, Washington, D.C. 20460





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

October 6, 1988

OFFICE OF
THE ADMINISTRATOR

Dr. Roger McClellan, Chairman
Clean Air Scientific Advisory Committee
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Sincerely,

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Mark J. Utell, MD
Chairman
Acid Aerosol Subcommittee

ACID AEROSOL SUBCOMMITTEE
RECOMMENDATIONS TO THE
CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

ON

POSSIBLE LISTING OF ACID AEROSOLS AS A CRITERIA AIR POLLUTANT

FINAL SUBCOMMITTEE REPORT
OCTOBER 6, 1988

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
WASHINGTON, DC

ABSTRACT

Under Section 109 of the Clean Air Act, the U.S. Environmental Protection Agency (EPA) is required to periodically review national ambient air quality standards (NAAQS) and the criteria on which they are based. The Act also requires the Clean Air Scientific Advisory Committee (CASAC) to provide scientific advice on any additional knowledge that is required to evaluate existing, or setting new or revised NAAQS. To evaluate the health effects of the class of air pollutants known as acid aerosols, the Committee requested that EPA prepare an "Acid Aerosol Issue Paper". This Issue Paper was reviewed by the Acid Aerosol Subcommittee of CASAC in June 1988. This report presents the conclusions and recommendations of that Subcommittee as transmitted to the CASAC.

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2.0 Options facing the Subcommittee

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1) Recommend that the Administrator consider listing acid aerosols under Section 108 of the Act. This implies a judgment that the available health effects information is compelling enough to require additional protection beyond the current NAAQS. Within 12 months of a listing decision, EPA must issue air quality criteria and propose standards.

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3.0 Major Research Findings that Support the Subcommittee Recommendations

The majority vote was based on the weight of evidence from research involving the three disciplines of animal toxicology, controlled clinical exposures, and epidemiologic studies. The key findings from recent toxicology research include: in chronic daily exposures of rabbits ($250 \mu\text{g}/\text{m}^3$ for 1-hr/day, 5 days/week for one year) persistent alterations of mucociliary and alveolar particle clearance, airway reactivity, airway secretory cell density and characteristics, and airway caliber changes were produced (Gearhart and Schlesinger, 1988). Such changes were similar to those produced by chronic exposure to cigarette smoke, suggesting that chronic bronchitis could result from more prolonged exposures. Furthermore, in single 3-hour and 5 days of 3-hour daily exposures to ultrafine acid coated zinc oxide particles with sulfuric acid concentrations in the range of $20\text{-}30 \mu\text{g}/\text{m}^3$, guinea pigs developed persistent changes in vital capacity, airway compliance, lung permeability, and carbon-monoxide diffusing capacity (Amdur and Chen, 1988). Similar results were obtained with $200 \mu\text{g}/\text{m}^3$ of ultrafine droplets of pure sulfuric acid. These findings suggest that primary and secondary sulfuric acid occurring as coatings on ultrafine fly ash particles may be considerably more toxic than secondary acidic aerosol which is found in the atmosphere in solution droplets.

Recent data from controlled clinical studies lends additional support for a relationship between exposure to near ambient levels of acid aerosols and adverse respiratory effects. In 1983, Koenig et al., (1983) identified allergic adolescent asthmatics as a subgroup responsive to inhalation of $100 \mu\text{g}/\text{m}^3$ sulfuric acid aerosols (30 minutes at rest followed by 10 minutes of exercise). These researchers have extended further their observation in allergic adolescent asthmatics linking exposure to near ambient levels of sulfuric acid at $68 \mu\text{g}/\text{m}^3$ with significant alterations in lung function (Koenig et al., 1988). The FEV_1 decreased 6% after inhalation of sulfuric acid using the previously described exposure protocol vs 1% decrease after breathing air. Furthermore, the most recent findings from Bauer et al. (1988) support Koenig's findings in that adult allergic asthmatics showed greater decrements in FEV_1 breathing $75 \mu\text{g}/\text{m}^3$ sulfuric acid vs. NaCl (control) for 2 hours in an environmental chamber. Based on our understanding of the current

data base, extrapolation to longer exposures coupled with more rigorous exercise could serve to intensify the response.

Data linking acid aerosols with respiratory health effects emerges from the ongoing field studies. Speizer (1988) showed that bronchitis in 10-12 year old children in four U.S. cities varied from about 3-11% from standardized questionnaire responses in direct relation to annual average concentration of aerosol H^+ , with the highest prevalence in the community with the highest annual average H^+ concentration which was 1.8 ug/m^3 (expressed as sulfuric acid equivalents). Similar associations were seen for other respiratory symptom responses in the same population. While the prevalence data were for the 1981 school year and the concentration data were for 1985-1988, it has been established in other studies from the six cities group that the bronchitis prevalence in these cities were in similar proportion in this population in other years, and that there was little variation in annual average pollution levels during these years. There were occasional exceedences of the current NAAQS for PM and SO_2 in some of these communities during some of the years covered by these studies, nevertheless, the Subcommittee is concerned that the current NAAQS may not provide adequate protection against such health effects.

4.0 Review of Issue Paper

The draft Issue Paper was generally considered to be well prepared and comprehensive. Most members of the Subcommittee provided detailed written comments concerning the draft to the Agency during and following the June 14-15, 1988 meeting. Extensive discussion occurred during the meeting which pointed out the need to address certain issues further. An example of such an issue is to define the pollutant indicator to regulate, its form, and measurement methodology.

5.0 Subcommittee Recommendations to CASAC

Following a careful review of the Issue Paper and extensive deliberations, members of the Subcommittee voted and reached the nearly unanimous conclusion¹ that the Clean Air Scientific Advisory Committee should recommend that the Administrator consider listing acid particles as a criteria pollutant. However, one Subcommittee member was in favor of recommending that the Administrator not consider listing acid particles, and one member was in favor of recommending that the Administrator defer such a decision until further research was completed. The minority positions are presented first.

¹ The Subcommittee vote was: 9 in favor of recommending that the Administrator consider listing, 1 in favor of recommending that the Administrator not consider listing, and 1 in favor of recommending that the Administrator defer judgment pending further research.

5.1 Recommendation to Defer Decision (Dr. Robert Phalen)

1) Although there is scientific evidence that airborne acidity at or near levels found in the environment is capable of harming respiratory tract tissues, I recommend that the decision to list acid aerosols as a NAAQS be deferred pending further research directed at resolving several basic issues. First, it is not at all clear just what the relevant air contaminant is. Airborne acidity can be in vapor forms and in particulate forms. In some cases, the acid vapor exceeds the particles in total mass. The full combination - that is the total acid present in all forms - is the logical agent to consider for listing because that is what is inhaled. This is also valid scientifically as many of us believe that an aerosol consists of a two-phase system of particles and a surrounding gas. However, the Subcommittee did not agree to include vapor phase acidity. Further research will very likely show that "total available hydrogen ion per unit volume of ambient air" is the entity that relates to adverse biological effects. Until this research is done our recommendation to list will possibly ignore a major fraction of the potentially hazardous agent and thus may under-protect exposed populations.

2) Next, the presently available human clinical exposure studies are for short periods - usually less than two hours. Because populations will be exposed for very prolonged periods additional studies are desperately needed. Longer exposures may show that effects increase upon longer exposure or alternatively that effects disappear upon longer exposure. Such studies are critical to defining whether peak levels of acidity or some integrated measure of acid exposure should be listed. Without this clarification substantial over-protection or under-protection could result.

3) Finally, we do not presently have enough animal toxicology data to identify the most sensitive sites in the body with respect to acid injury. One must have such information in order to project what human sub-populations are at greatest risk and what the expected risks are.

4) Certainly the acid aerosol issue should not be dropped. The available evidence indicates the real potential for airborne acidity contributing to adverse effects in human populations. However, until the above basic issues are better understood it is difficult to envision the establishing of a proper NAAQS.

5.2 Recommendation Not to List (Dr. George Wolff)

1) Health effects due to acid aerosols have been demonstrated in controlled exposures but only at concentrations which are much greater than an order of magnitude higher than typical ambient levels. Even the highest concentration ever reported in the ambient air is significantly lower than the

lowest documented concentration ever associated with a physiological response.

2) The assumption that the threshold dose for an adverse health effect is $100 \mu\text{g}/\text{m}^3\text{-hr}$ (i.e., $100 \mu\text{g}/\text{m}^3 \times 1 \text{ hour} = 10 \mu\text{g}/\text{m}^3 \times 10 \text{ hours}$) is not supported by any of the data. In fact, it is contrary to conventional wisdom because the body produces ammonia which will neutralize a certain amount of the acidity.

3) I question the accuracy of the ambient data, particularly the extreme values, since there is no standard procedure for measuring acid aerosols and the techniques used have not been subjected to rigorous quality assurance protocols.

5.3 Majority Conclusions - Recommendation to List²

Based on its assessment of the technical and scientific information presented in the Issue Paper, the Subcommittee reached a nearly unanimous conclusion that the Clean Air Scientific Advisory Committee should recommend that the Administrator consider listing acid particles as a criteria pollutant. In the Subcommittee's view, the cumulative evidence provided by the available animal, controlled human exposure, and epidemiologic studies clearly suggests possible health effects associated with exposure to acid particles. The Subcommittee recognizes that the available data base is not complete but is concerned by the potential health risks resulting from exposures under typical ambient conditions. The Subcommittee concluded that the weight of the evidence from the disciplines of animal toxicology, controlled clinical studies, and epidemiology is sufficient at this time to recommend that the Administrator consider listing of acid particles as a criteria pollutant.

In arriving at its recommendation, the Subcommittee took into account that research currently underway should begin to provide needed supplemental information in the next several years. To further augment these ongoing efforts, the Subcommittee has also identified key research needs that the Agency should begin to address immediately through a balanced and adequately funded research program. These are discussed in the separate report on acid aerosol research recommendations.

2 These nine members were: Dr. Mary Amdur, Dr. Doug Dockery, Dr. Robert Frank, Dr. Timothy Larson, Dr. Morton Lippmann, Dr. Gilbert Omenn, Dr. Marc Schenker, Dr. Jerome Wesolowski, and Dr. Mark Utell.

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APPENDIX A

Roster of the CASAC Acid Aerosol Subcommittee

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