Alliance OF AUTOMOBILE MANUFACTURERS

September 1, 2004

Dr. Deborah Drechsler, Ph.D.
Air Resources Board
Research Division
P.O. Box 2815
Sacramento, CA 95812-2815

Subject: Alliance Comments on Review of the California Ambient Air Quality Standard (AAQS) for Ozone

Dear Dr. Drechsler,

The Alliance of Automobile Manufacturers would like to thank the Air Resources Board for the opportunity to comment on the proposed changes to the California AAQS for ozone. We support ARB's goal to set air quality standards that protect human health and encourage the use of a sound scientific basis for those standards. We have reviewed the documents and identified several concerns with the scientific review and the resulting AAQS as proposed. The attached comments contain a detailed analysis of the material in the subject review document as well as specific recommendations, which if implemented, will strengthen the scientific discussion. Our main concerns are as follows:

The appropriate measurement of background ozone must be considered as part of the proposed AAQS. This issue will impact whether the proposed standards overlap with natural (or transported from outside of California) levels of pollutants in the air. The staff review uses one model (Fiore et al.) to evaluate background ozone concentrations. We identify specific concerns with that modeling approach and present analyses and data from a variety of sources that conflict with the assessment. The scientific literature on background ozone indicates that the proposed standards overlap with background concentrations. We also provide an analysis demonstrating that the elimination of essentially all human activity in California will still leave portions of California unable to attain the proposed standards. We recommend a broader discussion of background level ozone in the document, including natural fluctuations and measurements at clean sites to allow comparison of concentrations with the proposed standards. We also note that, from a policy perspective, the overlap of background concentrations with the proposed standards is in conflict with implementation requirements for California air districts to develop plans to meet the standards.

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The correlation between measured clinical health effects and impact on public health has not been established. The review does a comprehensive job of summarizing the available data on controlled exposures to ozone. However, the clinical exposure scenarios and interpretation of the potential public health impacts may not be representative of the public's true exposure to ozone. The controlled studies were primarily conducted comparing the physiological effects of the concentrations of 0.08 ppm ozone with clean, filtered air (zero ppm ozone concentration). Two specific areas where this may cause some concern include:

- New information regarding the mechanism of ozone effects suggests that a neural mechanism is the principal mechanism for ozone responses such as pulmonary function and respiratory symptoms. The possibility of attenuation of these effects in the literature suggests that changes in absolute ozone levels may greatly impact any observed effects. Therefore, studies comparing 0.08 ppm ozone to background levels may have different results than studies comparing to clean air.
- Studies of FEV1 changes as a function of ozone concentration also suggest that statistically significant effects on FEV1 may not be present if analyzed at levels between 0.08 ppm and background levels.

We recommend that ARB consider the new literature regarding biological mechanisms and impact of comparisons with background level ozone (versus zero ppm ozone) and use this information to reconsider the current interpretation of the health effect studies. In addition, we recommend the draft report clarify the effects of the studies that correspond to the American Thoracic Society's criteria for adverse health effects.

The inherent weaknesses in epidemiology studies need to be formally recognized. As widely discussed as part of the U.S. EPA's ongoing review of the PM NAAQS, inherent limitations of epidemiology include publication bias associated with reported epidemiology studies, inability of epidemiology to provide clear causal relationships, model specifications, stratification of data, confounding of the data, and inconsistent data analysis. These significant limitations during the application of epidemiological studies undermine our confidence in the outcomes of these studies. We recommend that the staff review the new literature discussed in the attached comments and consider these in the discussion of the epidemiology studies. Based on these significant issues inherent in the epidemiological studies, we would like ARB to reconsider the direct link of ozone to adverse health effects based on evidence indicated by the epidemiological studies.

The selected margin-of-safety interval has not been quantified or substantiated. Although there have been many studies performed at 0.08 ppm ozone there seems to be little data that shows a correlation to adverse health at levels below that concentration. The not to exceed form of the standard in itself should be considered as providing a margin of safety. Various controlled exposure, epidemiological and animal toxicity studies have shown inconsistencies in the response to ozone exposure. The U.S. EPA risk assessment has shown that at even higher ambient concentration exposures than ARB is considering, a limited number of repeat exposures has a minimal impact. We recommend that a risk assessment be performed to determine the extent of the margin of safety required to minimize risk to the most susceptible populations, with consideration given to a more statistically robust “form” of the standard, such as EPA's “averaging,” to account for natural fluctuations of ozone. We have also attached our previous review analyzing this important issue.

A more iterative process would allow for enhanced scientific data and opportunity to reconcile differences in the interpretation of the science. In order to sufficiently address these core issues with ARB’s scientific analysis and determination of the appropriate AAQS for ozone, we strongly encourage ARB to adopt a more iterative standard setting and approval process. This would naturally provide ample opportunity for ARB Staff to collaborate with their counterparts at the U.S. EPA in order to establish a common understanding of the science, to provide for a comprehensive explanation of any differences in interpretation of the science, and to reconcile legitimate differences and questions through further research if necessary. We consider it likely that by exploring such differences in interpretation of the science, the increased dialogue and the resulting debate will assist ARB in setting a standard based on sound science and will serve to abate some of the concerns of our industry and other interested stakeholders.

Please find our detailed comments enclosed. Again, we appreciate the opportunity to voice these concerns and look forward to ARB’s response on each issue. We welcome further dialogue and engagement in ARB's review process. Should there be any questions or manner in which we may be of additional assistance, please contact us.

Sincerely,

Casimer J. Andary
Director, Regulatory Programs

cc: R. Bode
B. Croes

Comments on June 21, 2004 Public Review Draft “Review of the California Ambient Air Quality Standard for Ozone”

By
Jon M. Heuss and Dennis F. Kahlbaum
Air Improvement resources, Inc.

Prepared for the
Alliance of Automobile Manufacturers

September 1, 2004

The California Environmental Protection Agency (CalEPA) made a public review draft available on June 21, 2004 of a joint report by the staffs of the Air Resources Board (ARB) and the Office of Environmental Health Hazard Assessment (OEHHA) entitled “Review of the California Ambient Air Quality Standard for Ozone.” The draft report reviews the science of ozone formation, exposure patterns, and ozone health effects and provides staff’s recommendations for revisions to the California ozone air quality standard. In particular the staff recommends retaining the current California 1-hour standard of 0.09 ppm while establishing an 8-hour average standard of 0.070 ppm. Both standards are defined as concentrations “not to be exceeded.”

Comments on Process

There is concern that the process used by ARB/OEHHA may not allow enough time for a robust scientific review of the proposed air quality standard. In California, the review of the relevant science and the policy recommendations based on the science are prepared before any public or outside scientific review. Although this joint effort expedites the rulemaking process, it does not allow external scientific sources to thoroughly review the scientific data and bring to ARB's attention other contradictory scientific literature that would affect the ensuing policy choices prior to any proposed regulatory action. In the federal case, the USEPA first prepares a Criteria Document (CD) that summarizes the science involved in a given pollutant. Then staff prepares a staff paper (SP) that translates that science into a range of policy options for the Administrator. The Clean Air Scientific Advisory Committee (CASAC), established under the federal Clean Air Act, provides iterative input into EPA staff and the Administrator on both the CD and SP. There is also public input as various drafts of the CD and SP are prepared and refined. Finally, the Administrator publishes a notice of proposed rulemaking that is subject to public review and comment before a final decision is promulgated. We would urge ARB/OEHHA to incorporate the staged nature of the federal review process into its analysis so public and outside peer review of the science occurs before policy options or recommendations are prepared.

The short time for public review is of concern. Given the sheer bulk of the documents and the number of references along with the wide range of disciplines that are involved in reviewing the science, an extended timeframe for public review would allow more time to fully evaluate all the factors and complexities that are needed to inform the public policy choices.

Comments on Draft Review Document

In the following sections, we provide comments on several chapters of the draft review document, focusing in particular on the science as it is informs the policy decision as to California ozone standards that protect the public health. In particular, we identify several factors that were not adequately considered during the development of the OEHHA and ARB recommendations. Finally, we comment on the basis for the OEHHA recommendations.

Chapter 4 Background Ozone in California

Although the Chapter properly articulates the various sources of ozone in the troposphere and properly focuses the discussion on policy-relevant background, it does not provide a balanced summary of the literature on the contributions of various sources. The select literature used makes a case that natural background has a maximum of 0.04 ppm (40 ppb) and that other exogenous contributions are small and unlikely to alter peak concentrations. It relies heavily on one modeling study, Fiore et al. 2002, to support its case. Although the review acknowledges that stratospheric intrusions can increase ozone in the troposphere, it also argues that these events will be recognizable in air quality records and easily identified as exceptional events.

There are several concerns with the analysis. First, it relies on one modeling study and does not account for known criticisms and limitations of the model. Second, we have found a large body of ozone observations that show annual maximum ozone concentrations in remote monitoring sites in the western United States that equal or exceed the proposed 8-hour standard. Third, the conclusions of several other researchers and the USEPA concerning maximum background levels should be considered in the review. Fourth, there are studies of stratospheric ozone, which demonstrate that its impact is larger, more widespread, and more difficult to identify than assumed in the review. Fifth, the review uses the standard as the typical case when various background studies shows it is an extreme value. Sixth, the analysis of background is not consistent with the background assumed by ARB in its assessment of the impact of transported pollutants on ozone in California. Each of these problems will be discussed in turn.

This issue will impact whether the proposed standards overlap with natural (or transported from outside of California) levels of pollutants in the air. Our review shows that the scientific literature on background ozone indicates the proposed standards overlap with background concentrations. We also provide an analysis demonstrating that the elimination of essentially all human activity will still leave portions of California unable to attain the proposed standards. We recommend a broader discussion of background level ozone in the document, including natural fluctuations and measurements at clean sites to allow comparison of concentrations with the proposed standards. We also note that from a policy perspective, the overlap of background concentrations with the proposed standards is in conflict with implementation requirements for California air districts to develop plans to meet the standards.

Problems with the Fiore et al. 2002 Modeling Study

The review relies on the Fiore et al. 2002 modeling study to estimate the various components of background ozone. There are a number of problems with this approach. First, it is a model calculation with a global transport model that was not designed to address the components of background specifically in California. The model was run for the summer of 1995, so it was not aimed at evaluating the various sources of ozone over the entire year. As documented in the following, it is not a reliable tool to estimate the mean value or the range of background in California that might influence the attainability of the proposed standards.

The GEOS-CHEM model Fiore et al. used employs a coarse 2^{o} latitude by 2.5^{o} longitude horizontal grid that the authors acknowledge cannot resolve the steep gradients in surface heating near coastal sites that determine the depth of the mixed layer. The authors indicate that this compromises the simulation over coastal urban environments. In addition, the authors list the inability to resolve topography in California as another problem that manifests itself in the Central Valley of California. The limitations of the model in simulating coastal urban environments and the Central Valley are important in that these are the areas of California with the greatest population and hence man-made emissions.

A source of non-anthropogenic ozone that is important in California is photochemical production from reactions of NOx that comes from microbial action in the soil and lightning with biogenic hydrocarbons from vegetation. Another complicating factor in California is increased NOx emissions from soil related to fertilizer use. The model was not designed to accurately simulate these sources and processes in California.

Any global model contains many assumptions and simplifications that simply cannot be fully evaluated. The GEOS-CHEM model is but one of a number of such models. Fusco and Logan 2003[1] evaluated the GEOS-CHEM model and report that the model estimates somewhat higher production and loss rates of ozone than other chemical transport models, as much as 15 to 30 %. Since the net photochemical production of ozone is determined by the difference between these two large numbers (a large chemical source term and a large chemical sink term), the net production cannot be precisely determined. They note that differences in modeled photochemical production and loss rates affect the relative importance of the stratospheric source giving examples of other models that indicate a much larger role for the stratospheric source in summer and in

[1] A. Fusco and J. Logan, "Analysis of 1970-1995 trends in tropospheric ozone at Northern Hemisphere midlatitudes with the GEOS-CHEM model," J. Geophys. Res., **108**, No. D15, 4449 (2003).

winter. Adding to the complexity is that assumptions have to be made about the cross-tropopause flux of ozone and ozone deposition at the surface, quantities that each have significant uncertainty, too.

There are other aspects of the chemical transport models that are also highly uncertain. For example, there is disagreement over how many ozone molecules are produced, on average, from each NO molecule emitted. The recent NARSTO Synthesis Report[2] indicates that more recent studies have reduced the estimated ozone production efficiency from 7 to 10 molecules ozone per molecule NOx emitted down to 1 to 3. In addition, the NARSTO report acknowledges there is substantial disagreement over key factors such as the magnitude of U. S. biogenic VOC emissions (uncertain by a factor of 2 or 3) and natural NOx emissions from soil and lightning.

Fusco and Logan also express concern that with the accuracy of the method imposed to simulate the annual flux of ozone across the tropopause, noting that an incorrectly modeled seasonal cycle, as appears likely in the case of the GEOS-CHEM model, could adversely affect the response of the modeled ozone to the stratospheric flux. In summary, there are a large number of questions concerning the conclusions derived from the model, in general, and more specifically in California. Thus, it is not a reliable tool to estimate mean background in California much less the range of background that might influence the attainability of the proposed standards.

Recent Measurements of Peak Ozone in the Western United States

Since the staff recommends that the proposed standards be defined as concentrations not to be exceeded, the Chapter should evaluate the extreme values or yearly maxima of policy relevant background. There is now a substantial body of ozone observations that shows annual maximum 8-hour ozone concentrations in remote monitoring sites in the western United States that equal or exceed the staff's proposed 8-hour standard. This data is relevant to the issue of a regional, policy relevant background that will hinder the attainability of the proposed standard. Therefore, it should be included and discussed in the Chapter.

In California, the ARB has provided the peak 8-hour indicators for all the air basins in the 2004 Almanac as well as in Chapter 7. The yearly maximum 8-hour concentrations in Lake County have averaged 0.069 ppm for the past 20 years and equaled or exceeded 0.07 ppm in 11 of the past 20 years. In the North Coast, the yearly maxima have averaged 0.072 ppm over the past 20 years and equaled or exceeded 0.070 ppm in 13 of the past 20 years. Inspection of the figures in Chapter 7 shows that the proposed 0.070 ppm standard would put the entire state out of attainment.

As the USEPA has gone through the attainment designation process for the new federal 8-hour standard, individual states submitted their ozone data. Several western governors submitted data from remote sites that were in attainment of the federal 8-hour standard

[2] The NARSTO Synthesis Team, "An Assessment of Tropospheric Ozone Pollution: A North American Perspective," July 2000, pages 3-19 and 3-31.

but would exceed the proposed California 8-hour standard. For example, Governor Geringer of Wyoming[3] submitted data from the Pinedale ozone monitor in Bridger Teton National Forest for which the yearly maximum 8-hour ozone ranged from 0.066 to 0.075 over the previous decade. Similarly data from a monitor at the Yellowstone National Park Lake Lodge Area had yearly 8-hour maxima ranging from 0.058 to 0.078 ppm. Another monitor in the Medicine Bow National Forest had yearly ozone maxima from 0.069 to 0.084 ppm. The national data provided lends insight into the presence of regional background.

Many states submitted ozone data for the annual fourth highest 8-hour average for comparison with the federal standard. Utah was one such state. To estimate ozone levels in rural areas of Utah, Governor Leavitt submitted data[4] from National Park Service and other state monitoring networks surrounding Utah. The data from Mesa Verde, Grand Canyon, and Great Basin National Park Service sites and San Juan County in New Mexico had federal 8-hour design values ranging from 0.069 ppm to 0.075 ppm. Since the design value is the 3-year average of the 4^{th} highest 8-hour daily maximum, all four sites must have had yearly 8-hour maxima above 0.070 ppm.

To evaluate how widespread the yearly 8-hour maxima above 0.070 ppm are in the western U. S., we plotted the yearly maxima from all the sites in the USEPA AIRS database for 2001 through 2003. The 8-hour daily maximum values were determined for each site using the USEPA procedure. For each site, the yearly maximum of those 8-hour daily maxima was plotted on a map of the United States using different colors for yearly maxima in different ranges. The following figures show that almost all the sites in the western half of the nation have yearly maxima that approach or exceed the proposed California standard.

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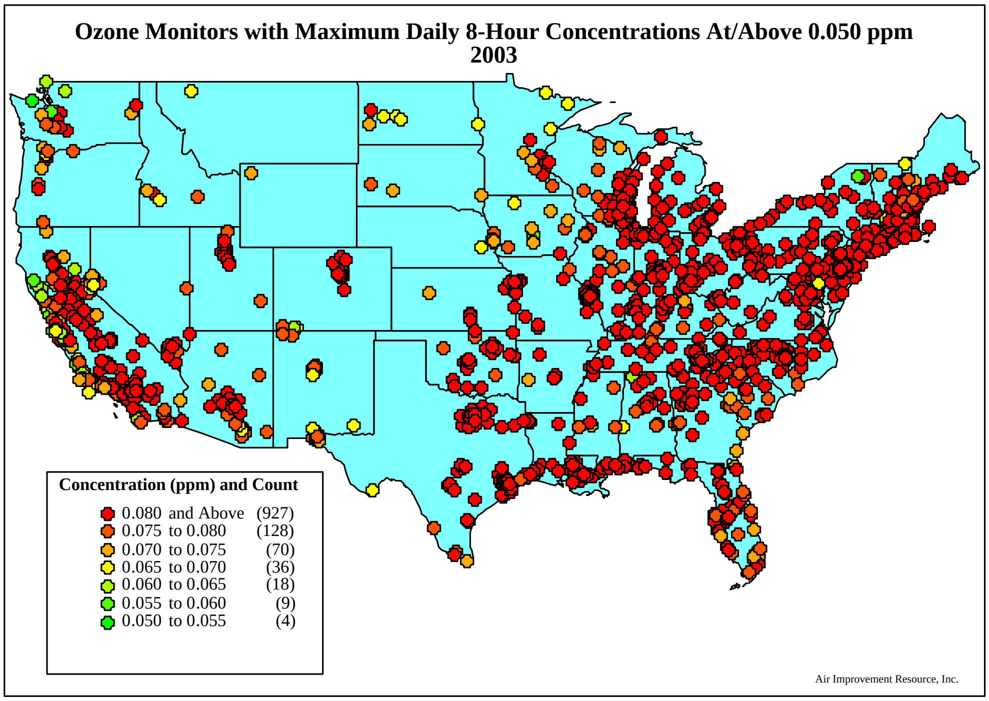
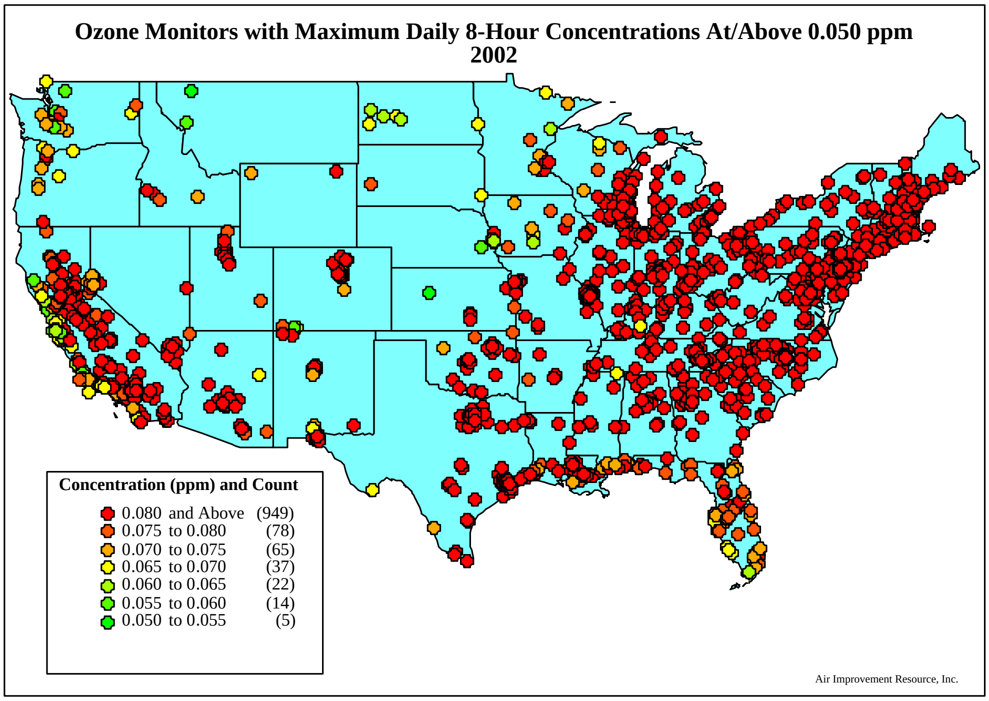
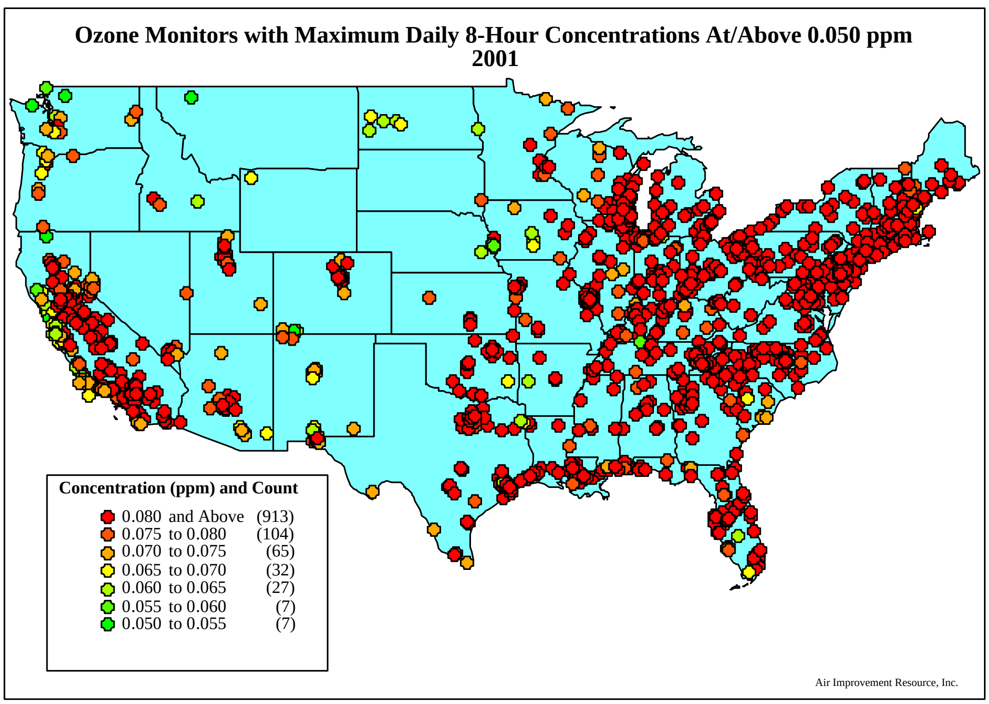
[3] See July 7, 2000 letter from Governor Jim Geringer to Ms. Rebecca Hanmer, Acting USEPA Region VIII Administrator and enclosures.

[4] See June 10, 2003 letter from Governor Michael Leavitt to Robbie Roberts, USEPA Region VIII Administrator and enclosures.



Ozone Monitors with Maximum Daily 8-Hour Concentrations At/Above 0.050 ppm
2003
Concentration (ppm) and Count
0.080 and Above (927)
0.075 to 0.080 (128)
0.070 to 0.075 (70)
0.065 to 0.070 (36)
0.060 to 0.065 (18)
0.055 to 0.060 (9)
0.050 to 0.055 (4)
Air Improvement Resource, Inc.


Ozone Monitors with Maximum Daily 8-Hour Concentrations At/Above 0.050 ppm
2002
Concentration (ppm) and Count
0.080 and Above (949)
0.075 to 0.080 (78)
0.070 to 0.075 (65)
0.065 to 0.070 (37)
0.060 to 0.065 (22)
0.055 to 0.060 (14)
0.050 to 0.055 (5)
Air Improvement Resource, Inc.


Ozone Monitors with Maximum Daily 8-Hour Concentrations At/Above 0.050 ppm
2001
Concentration (ppm) and Count
0.080 and Above (913)
0.075 to 0.080 (104)
0.070 to 0.075 (65)
0.065 to 0.070 (32)
0.060 to 0.065 (27)
0.055 to 0.060 (7)
0.050 to 0.055 (7)
Air Improvement Resource, Inc.

The first through fifth highest daily maximum 8-hour average ozone values through 2003 are available for national parks and monuments on the USEPA's AIRNOW web site. The period of record varies for each site, but for most there is about a decade or more of ozone 8-hour maxima. These data show that violations of the proposed California 8-hour standard would occur at many of the remote western sites. For example, the yearly 8-hour maxima from 1992 through 2003 range from 0.063 to 0.080 ppm at Canyonlands National Park in Southeast Utah where the ozone monitoring season is months 5 through 9. The yearly 8-hour maxima from 1983 through 2003 range from 0.058 to 0.080 ppm at Theodore Roosevelt National Park in Western North Dakota where the ozone monitoring season is also months 5 through 9. The yearly 8-hour maxima from 1989 through 2003 ranged from 0.067 to 0.084 ppm at Chiricahua National Monument in the Southeast corner of Arizona where the ozone monitoring season is months 1 through 12.

To evaluate the sources of elevated ozone at remote California sites, Winkler and Chock[5] analyzed data from a number of national park sites. They identified examples of ozone above the proposed state standards at two generally clean sites and used trajectory analysis to determine the source areas for the elevated ozone. While some of the high ozone values at the sites were associated with trajectories that crossed major urban areas, there were also elevated ozone observations on days when trajectories show air coming from the Northern Pacific without passing near any significant population centers. This is strong evidence that some violations of the proposed state standards are associated with imported background ozone.

Previous Assessments of Maximum 1-Hour Background

As noted above, the Chapter should evaluate the extreme values or yearly maxima of policy relevant background. Since both 1-hour and 8-hour standards are proposed, the extreme values of both 1-hour and 8-hour ozone are of interest. Draft Chapter 4 does not account for the conclusions of several researchers and the USEPA regarding maximum background levels. Recently, Vingarzan[6] reported the range of annual maxima at background stations in the U. S. and Canada. The annual maxima (1-hour) at Western U. S. and Canadian background sites approached or exceeded 0.08 ppm. There have been several additional studies performed by Singh et al.[7], Logan[8], Lefohn and Foley[9], and Altshuller and Lefohn[10] that have stated that 1-hour background levels approach or exceed the 0.08 ppm.

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[5] Personal Communication from David Chock, Ford Motor Company

[6] R. Vingarzan, "A review of surface ozone background levels and trends," Atmospheric Environment, **38**, 3431-3442, 2004.

[7] H. B. Singh, F. L. Ludwig and W. B. Johnson, "Tropospheric ozone concentrations and variabilities in clean remote atmospheres," Atmos. Environ., **12**, page 2185, 1978.

[8] J. A. Logan, "Ozone in Rural Areas of the United States," J. Geophys. Res., **94**, D6, page 8511, 1989.

[9] A. S. Lefohn and J. K. Foley, "Estimated Surface-level Ozone Exposures in Selected Class I Areas of the United States," paper 91-144.2, presented at the 84th Annual Meeting of the Air and Waste Management Association, Vancouver, British Columbia, June 1991.

[10] A. P. Altshuller and A. S. Lefohn, "Background Ozone in the Planetary Boundary Layer Over the United States," J. Air & Waste Manage. Assoc., **46**, page 134, 1996.

When EPA revised the federal 1-hour ozone standard in 1979 to 0.12 ppm, the Agency acknowledged that:[11]

> “Field measurements at some remote sites, where man-caused ozone is likely to be negligible, have shown low-but not insignificant- rates of exceedances of the 0.08 ppm level originally proposed for the secondary standard.”

In 1989, Logan[12] reported the results of an analysis of ozone data from rural locations in the U. S. She reported that ozone concentrations above 80 ppb were common in rural areas of the eastern U. S. in spring and summer (occurring between about 2 and 8 % of the time) but were unusual at remote western sites, occurring less than 0.5 % of the time. She also pointed out that concentrations of NOx in rural areas of the east are frequently high enough to permit significant photochemical formation of ozone during favorable weather conditions, but that NOx is much lower in remote regions of the west. Logan also reported that the median ozone concentrations of 30 to 40 ppb were similar at rural sites across the country even though there is a much greater population and emission density in the eastern U. S. than in the western U. S.

Lefohn and Foley[13] reported in 1991 on an analysis of ozone data from 26 Class I national parks and wilderness areas. For the seven cleanest sites, the yearly maximum 1-hour average concentrations were in the range of 0.06 to 0.075 ppm.

In 1996, Altshuller and Lefohn[14] published an analysis of background ozone in the planetary boundary layer of the U. S. They selected 11 sites for analysis. The criteria they used included using sites receiving the cleanest air masses from the upwind flow off a continent or ocean, and sites isolated from the influence of urban plumes or regional ozone formation from anthropogenic emissions. They reported that the maximum 1-hour concentrations in the western United States in the April through October period ranged from 50 to 98 ppb and the maximum 1-hour concentrations at coastal sites ranged from 44 to 80 ppb.

When the USEPA estimated background ozone during a review of the federal ozone standard in 1996/7, the agency’s Staff Paper concluded:

> “…a reasonable estimate of the background O_3 concentrations near sea level in the U. S. for a 1-hour daily maximum during the summer is usually in the range of 0.03 to 0.05 ppm. At clean sites in the western U. S., the maximum annual hourly values are in the range of 0.06 to 0.075 ppm.” (OAQPS Staff Paper at page 20)

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[11] 44 Fed. Reg. 8212, February 8, 1979.
[12] J. A. Logan, “Ozone in Rural Areas of the United States,” J. Geophys. Res., **94**, D6, page 8511, 1989.
[13] A. S. Lefohn and J. K. Foley, “Estimated Surface-level Ozone Exposures in Selected Class I Areas of the United States,” paper 91-144.2, presented at the 84th Annual Meeting of the Air and Waste Management Association, Vancouver, British Columbia, June 1991.
[14] A. P. Altshuller and A. S. Lefohn, “Background Ozone in the Planetary Boundary Layer Over the United States,” J. Air & Waste Manage. Assoc., **46**, page 134, 1996.

Thus, there is a history of analyses in the literature as well as summaries by USEPA showing yearly maximum 1-hour ozone concentrations in locations described as remote sites, clean sites, or background sites that can approach or exceed 0.08 ppm. The current California 1-hour standard of 0.09 ppm is just above the maximum 1-hour values at these background sites. The ARB draft should acknowledge these analyses and conclusions for 1-hr ozone to show that the background level of the 8-hr standard may have similar occurrences of a wide range of values.

The idea that peak background is 0.04 ppm is inconsistent with the data from the cleanest of the California air basins where the population and emissions density is only a minute fraction of that in California. While transport from other more populated California air basins may play a role from time to time in the ozone values measured in the most remote air basins, the large fraction of daily 1-hour maximum and daily 8-hour maximum concentrations that are reported as 0.04 ppm and greater in the tables and figures in section 7.3.6 demonstrate a much higher policy relevant background than indicated in Chapter 4.

Evidence Regarding Stratospheric Ozone

There are some more recent studies that we would like to bring to the attention of the ARB staff. There is a body of studies of stratospheric ozone which demonstrate that its impact is larger, more widespread, and more difficult to identify than assumed in the draft report. It relies on one study of stratospheric/tropospheric exchange from Europe, Galani et al. 2003. However, the Galani et al. study, which evaluated events that reached Greece, is specific to the southern Mediterranean. The paper references several other European studies that were carried out in central and Western Europe as well as studies from other locales. Thus, there are many other relevant studies in the literature.

Ozone is formed in high concentrations in the stratosphere due to oxygen molecules absorbing short wavelength radiation from the sun (175 to 240 nm). In fact, the presence of stratospheric ozone (which absorbs the sun's radiation below 290 nm) protects humans and ecosystems by filtering out dangerous ultraviolet radiation. A major sink process for the ozone in the stratosphere is transfer into the troposphere and eventual destruction at the ground. Several mechanisms for stratospheric-tropospheric exchange have been postulated and studied. ARB mentions that there are two mechanisms of stratospheric intrusions, tropopause folding events and general stratospheric subsidence. Shapiro[15] actually summarizes eight mechanisms as follows:

> "The various meteorological processes by which air and its chemical constituents are exchanged between the stratosphere and troposphere may be summarized as 1) the mean meridional Hadley cell circulation; 2) the seasonal variation in the height and potential temperature of the tropical tropopause; 3) changes in the

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[15] M. A. Shapiro, "Turbulent Mixing within Tropopause Folds as a Mechanism for the Exchange of Chemical Constituents between the Stratosphere and Troposphere," J. Atmospheric Sciences, **37**, page 994, 1980.

> potential temperature and vertical displacement of the tropopause through radiative cooling above the jet stream and cumulonimbus cirrus clouds at the tropopause; 4) transverse mass circulations about subtropical jet stream systems; 5) vertical mass exchange during tropopause "folding" events associated with extratropical cyclonic systems; 6) cumulonimbus towers which penetrate the tropical and extratropical tropopause; 7) clear air turbulence (CAT) in the vicinity of jet streams (resulting from vertical wind shear instabilities within tropopause folds) and in the region of decreasing winds in the stratosphere above the jet core; and 8) weak eddy diffusion across the vast quiescent expanses of the tropopause."

The fifth mechanism, tropopause folding events (TFEs), is of particular interest because it has been amply documented that it inserts layers of high ozone concentrations into the troposphere.

Published observations of stratospheric ozone in the troposphere during intrusion events began appearing in the literature in the 1960's. In 1981, Johnson and Viezee[16] reported on the results of 10 aircraft flights during the spring and fall of 1978 mapping the structure of stratospheric ozone intrusions over the central U. S. They concluded:

> "The intrusions typically are characterized by peak ozone concentrations at higher altitudes (6-8 km) in the range of 240-400 ppb, diminishing to 100-200 ppb at lower altitudes as mixing with surrounding air occurs. The data show that stratospheric ozone intrusions are typically 100-300 km wide in the cross-wind direction, are several hundreds of kilometers long, and can be tracked down at least as far as the top of the atmospheric boundary layer (about 2 km). Possible mechanisms for downward transport within the boundary layer include normal convective mixing, organized convection associated with cloud and precipitation processes, and organized downward motion within frontal zones."

In a follow-up paper by Viezeee, Johnson and Singh,[17] the authors assessed the downward flux of ozone and its probable impact on ground-level ozone. They summarized and evaluated 17 aloft observations of stratospheric ozone made by aircraft or balloons and 10 published studies that in which elevated ground-level ozone measurements have been ascribed to stratospheric ozone. They estimated that direct ground-level impacts are infrequent (less than 1 percent of the time) and most likely are associated with ozone concentrations of 100 ppb or less.

One of the reasons that that direct ground-level impact seems rare is that, as documented by Johnson and Viezee, the ozone intrusion tends to become more nearly horizontal as it progresses toward lower altitudes. Viezee et al note:

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[16] W. B. Johnson and W. Viezeee, "Stratospheric Ozone in the Lower Troposphere- I. Presentation and Interpretation of Aircraft Measurements," Atmos. Environ., **15**, page 1309, 1981.
[17] W. Viezee, W. B. Johnson and H. B. Singh, "Stratospheric Ozone in the Lower Troposphere- II. Assessment of Downward Flux and Ground-level Impact," Atmos. Environ., **17**, page 1979, 1983.

> "Several investigators maintain that the stratospheric air reaches ground-level in about two days by way of surface high-pressure systems that follows travelling upper tropospheric low-pressure troughs. If this concept is correct, it will be difficult to quantify (on the basis of measurements) the stratospheric component of the near-surface ozone budget, since high-pressure areas also are favorable for air stagnation and surface transport of anthropogenic ozone."

Indeed, Wolff et al.[18] have reported on field studies in rural locations in Kentucky and North Carolina and a remote location in South Dakota. They found that ^{7}Be, a tracer of stratospheric air, is higher on the backside of high-pressure system than on the front side. Although there are limitations to using ^{7}Be as a tracer for stratospheric air, this finding suggests that a substantial amount of stratospheric ozone does mix to the ground under conditions where anthropogenic ozone formation is also expected.

Shapiro has also reported evidence for the seventh mechanism noted above - clear air turbulence (CAT) in the vicinity of jet streams (resulting from vertical wind shear instabilities within tropopause folds). He reports ozone concentrations of over 200 ppb over Southern California in March 1978.

With multiple mechanisms of stratospheric-tropospheric exchange and with multiple ways that stratospheric ozone may mix with tropospheric ozone, it is not surprising that there is a great deal of variation in free tropospheric ozone concentrations. In recent years, there has also been considerable interest in and study of long range transport of ozone and its precursors from Asia to the U. S., from the U. S. to Europe and from Europe to Asia. While many of these studies are referenced in the chapter, their implications for policy relevant background are not fully explored. Even with very sophisticated measurements and analyses, there are many instances where elevated ozone is observed in the atmosphere and it appears to be a mix of air of stratospheric origin and air from long-range anthropogenic transport. We recommend this issue be discussed in detail in the document given its potentially important implications.

Aircraft measurements over the eastern U. S. and western Atlantic during the spring of 1996 reported by Parrish et al.[19] confirm the significant variability in tropospheric ozone concentrations. In 72 hours of measurement during nine flights, ozone concentrations varied between 30 ppb and 285 ppb. The authors used the CO-ozone relationship to discriminate between stratospheric and anthropogenic influences. The authors indicate that strong stratospheric influences were observed on more than half the flights with ozone levels as high as 285 ppb. There was evidence of anthropogenic influence that resulted in net production of ozone at some times and net destruction of ozone at other times. Most data points reflected <u>both</u> stratospheric and anthropogenic influences

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[18] G. T. Wolff, M. A. Ferman and P. R. Monson, "The distribution of beryllium-7 within high-pressure systems in the eastern United States," Geophys. Res. Lett., **6**, page 637, 1979; N. A. Kelly, G. T. Wolff and M. A. Ferman, "Background pollutant measurements in air masses affecting the eastern half of the United States-I. Air masses arriving from the northwest," Atmos. Environ., **16**, page 1077, 1982.
[19] D. D. Parrish, T. B. Ryerson, J. S. Holloway, M. Trainer and F. C. Fehsenfeld, "New Directions: Does pollution increase or decrease tropospheric ozone in Winter-Spring?," Atmos. Environ., **33**, page 5147, 1999.

A study by Beekmann, et al.[20] used several techniques to evaluate the presence of tropopause folds. They report that:

> "on the average, folds occur twice as much in the Northern than in the Southern Hemisphere. In the Northern Hemisphere they are concentrated in the latitude band 40-70 degrees. On the average, 18.4 folds are simultaneously present in the Northern Hemisphere."

The number of simultaneous folds (estimated through analysis of a 10-year meteorological data set) is roughly four times the number estimated by Viezee, et al. in 1983. Beekmann et al. also refer to a 1996 study that shows tropopause folds are often detected in the front side of troughs, but also in their rear and in regions of zonal flow of the polar jet stream. With the meteorological analysis, Beekmann et al. found that significant tropopause folding activity was present over the ten-year period over the Northern Pacific as well as over California. (See Figure 2 of Beekmann et al.)

Emmons et al.[21] have compiled data for ozone and other chemical species from a number of aircraft studies into global maps. The maps provide information on ozone averaged onto 5 degree latitude by 5 degree longitude horizontal grids with 1 km vertical resolution. The available data show elevated ozone concentrations of between 40 and 100 ppb in the grids 6-8 km over the west coast of the U. S. in the March-April-May quarter (see Plate 1 of Emmons et al.). The data for other locations, heights and time periods demonstrate significant variability in tropospheric ozone levels. This large data set clearly demonstrates that ozone levels in the troposphere are highly variable, so that one cannot assume that the free troposphere is a well-mixed reservoir of ozone.

The text of the chapter indicates that TFEs are likely to be easily recognized. However, the known patterns of tropospheric folds together with the ground-level ozone-^{7}Be analyses by Wolff et al. suggest that stratospheric ozone also contributes significantly to ground-level ozone during times when man-made ozone is present. In addition to the examples in the references noted above, there are several cases in the references presently included in the chapter of elevated ozone transported long distances that contain a mixture of anthropogenic and stratospheric air.[22] In these situations, routine monitoring data will not be able to distinguish the anthropogenic contribution from the stratospheric contribution. Although the ARB and the USEPA have "exceptional event" policies, it is likely that only a small portion of the stratospheric intrusions that affect ground-level ozone concentrations will be uniquely identified and thereby qualify for the exceptional event policy.

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[20] M. Beekmann, G. Ancellet, S. Blonsky, D. DeMuer, A. Ebal, H. Elbern, J. Hendricks, J. Kowol, C. Mancier, R. Sladkovic, H. G. J. Smit, P. Speth, T. Trickl and Ph. Van Haver, "Regional and Global Tropopause Fold Occurrence and Related Ozone Flux Across the Tropopause," J. of Atmospheric Chemistry, **28**, page 29, 1997.

[21] L. K. Emmons, D. A. Hauglustaine, J-F. Muller, M. A. Carroll, G. P. Brasseur, D. Brunner, J. Staehelin, V. Thouret and A. Marenco, "Data composite of airborne observations of tropospheric ozone and its precursors, " J. Geophys. Res., **105**, D16, page 20,497, 2000.

[22] See Trickl et al. 2003 and Jaegle et al.2003.

We would like to see this available literature included in the review of the role of stratospheric ozone on ground level background. It appears from these other studies cited that the Galani et al. study is not typical of Europe or of the U. S.-relevant studies.

Problems with Comparing Average Behavior with an Extreme Value Standard

Chapter 4 focuses on background as it may apply to the stable, stagnant conditions that produce the highest ozone concentrations from man-made emissions. For example, it is argued that some background sources generally peak in other seasons than man-made ozone and that they are generally not major contributors to observed peak ozone. However, the review proposed an extreme value standard that applies everywhere in California all the time. So the range of background during worst case urban episodes is not the only concern. The evidence from observations around the globe and modeling is that the factors and processes that affect ozone levels in the atmosphere are very complex. There are complex chemical and dynamic processes involved that interact in a variety of ways. Stratospheric intrusions create elevated ozone plumes that may persist or mix with neighboring air. Under certain conditions, long-range transport of man-made ozone or its precursors from continent to continent is observed. Large-scale plumes originating in the stratosphere and plumes from long-range transport and plumes from nearby urban areas can all cause elevated ozone levels exceeding the proposed state standards. Sometimes ozone from these sources is mixed together so that one cannot identify a specific source. It just takes one combination of the many different combinations of these sources to violate the state standard.

The Background Used in ARB Transport Assessments

The March 2001 ARB Staff Report, in reference to background level ozone, states the following:

> "For instance, clean air, such as the air mass over the Pacific Ocean has a normal background of 4 pphm. Areas in the mountains may have background concentrations of 5 or 6 pphm…" (March 2001 Staff Report at page D-2)

Since 4 pphm is the same as 0.04 ppm or 40 ppb, the ARB, in assessing transport, considers the normal or average clean air background coming off the Pacific to be 0.04 ppm. This contradicts the statement on page 4-11 that the maximum clean air background is 0.04 ppm. The "clean air" boundary conditions used in photochemical modeling also specify 0.04 ppm ozone because it is widely accepted as an average clean air background. The normal background at elevation noted in the March 2001 Staff Report of 0.05 or 0.06 ppm is very close to the proposed 8-hour standard of 0.070 ppm, so that fluctuations around the normal background will likely cause violations of the proposed standard.

Policy Relevant Background Levels

Given that the extreme values of background can approach or exceed the proposed standards, the proposal allows little or no room for ozone from mankind's activities. With a policy relevant background that varies substantially, there will be times and places where the background approaches the 70 ppb level of the proposed 8-hour standard. The Chapter limits the discussion of policy relevant background to the meteorological conditions conducive to peak urban ozone formation. While this is currently the limiting case for development of control plans, it may not be under a 70 ppb standard.

If the policy relevant background is 40 ppb and the standard is 70 ppb, the amount of ozone that can be formed from man-made emissions is only 30 ppb. So even with a 40 ppb background, the proposed standard allows little room for man's activities. On a day when the background is 60 ppb, the margin for man's activities will be only 10 ppb. On a day when the background is 70 ppb, there is no margin for man's activities. While this illustration over-simplifies the complex chemical and meteorological processes involved in ozone formation and transport, it demonstrates that transport of ozone from upwind natural and non-California man-made sources can make the proposed standard unattainable.

Even with a 40 ppb background advected into the South Coast Air Basin, the degree of emission control required to attain a 70 ppb standard is unreasonable. The Alliance of Automobile Manufacturers asked ENVIRON International[23] to carry out photochemical modeling of Southern California to investigate whether an 8-hour ozone standard of 0.070 ppm could be achieved in California under any reasonable level of emission reductions. ENVIRON used the latest photochemical modeling database and models from the South Coast District's 2003 Air Quality Management Plan (AQMP). Using clean boundary conditions taken from the 2003 AQMP to develop initial conditions and boundary conditions that do not reflect the presence of any anthropogenic emissions, ENVIRON simulated the ozone formation for the August 3-7, 1997 episode that was used in the AQMP. With the 2003 AQMP fully implemented (310 Tons per day VOC and 530 tons per day NOx) the peak 8-hour values ranged from 91 to 104 ppb which is substantially above the 70 ppb proposal. However, with even 90 % reduction in VOC and NOx beyond the reductions in the AQMP (31 tons per day VOC and 53 tons per day NOx), the peak 8-hour ozone on one of the days of the episode was above the 70 ppb proposal (either 79 or 82 ppb depending on whether the emissions were allocated under Control Option 1 or 2 of the AQMP). Only when all anthropogenic emissions in the modeling domain turned off (both U. S. and Mexican) was the peak 8-hour ozone during the episode was 37 to 46 ppb.

To put this in context, the current 2005 baseline emissions are 752 tons per day for VOC and 952 tons per day for NOx. Thus, even 95 % additional control of the man-made

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[23] ENVIRON International Memorandum from R. Morris and S. Lau to C. Andary of the Alliance of Automobile Manufacturers, August 17, 2004.

VOC and NOx from current 1995 baseline is not enough to attain the proposed 8-hour standard. To provide further context, the current baseline emissions are the result of many decades of control efforts in the Basin that have drastically reduced man-made emissions per unit of economic activity or per vehicle mile driven. This has allowed the Basin to grow in population while ozone pollution has decreased substantially. The difficulty in finding additional emission reductions to enable the South Coast to attain the federal 1-hour standard is well known. It has led to the use of long-term or “black box” emission reductions within the Basin in order to demonstrate attainment of the federal 1-hour standard.

ENVIRON also made calculations for other air basins in Southern California. The 90 % control of man-made emissions beyond the 2003 AQMP did bring these air basins below the 70 ppb proposal, but when Mexican emissions were added back in, the proposed 8-hour standard was exceeded in the San Diego and Salton Sea air basins.

The ENVIRON modeling demonstrates that the proposed standard will not be achievable throughout California. These calculations are for only one episode, a high ozone case, but a best case situation in terms of background. The boundary conditions and initial conditions were representative of extremely clean air and no transport was included from Mexico. In addition, the biogenic inventory for the AQMP did not include NOx emissions. The biogenic VOC inventory for the modeling domain varied from 584 to 852 tons per day, but there was no biogenic NOx in the inventory. This omission is probably not important for the AQMP itself, but it would be important in any tests of the ozone formed from elimination or almost total elimination of man-made NOx. Therefore, the simulations would be expected to understate the ozone from natural sources.

For other situations in which there is an additional contribution from natural sources or transport of non-California man-made ozone or ozone precursors, the margin for man-made ozone associated with the 70 ppb standard will be reduced. In much of California, the reactions of biogenic NOx emissions (that maybe increased due to fertilizer use) and biogenic VOC will contribute additional uncontrollable ozone that will add to the regional background coming off the ocean.

Summary of Chapter 4: Background Ozone in California

In summary, the scientific literature on background ozone indicates that it is highly variable and can reach levels close to the current California 1-hour standard. There is ample evidence that the proposed 8-hour standard will be exceeded, as a result of the regional background from natural and non-California sources, in all California air basins and throughout much of the Western U. S. including many national parks.

The ARB discussion of background relies on an unverified model calculation and discounts the large body of observations and analyses around the world that indicate higher maximum background concentrations than ARB assumes. In addition, the scientific literature and the USEPA ozone scientific review support a higher maximum background than ARB assumes. The review states that the influence of tropopause folding events that insert high concentrations of ozone from the stratosphere into the troposphere will be easily recognized and dealt with by the exceptional events policy. However, as documented in the references noted above, there is evidence that these events may not be easily identified. The policy relevant background varies spatially and temporally. It varies substantially on both seasonal and short-term time scales, and policy relevant background levels leave little room for man's activities. Based on all the studies and analysis above, the Alliance requests that ARB consider revising this chapter on background to include these studies.

Chapter 5 Ozone Precursor Sources and Emissions

Chapter 5 focuses on anthropogenic emissions of ozone precursors. However, since the proposed 8-hour standard of 0.07 ppm would be exceeded throughout the State as well as throughout the rest of the Western United States, the question of whether the standard could be achieved with even total elimination of man-made precursors in California is at issue. To provide perspective, the Chapter should include estimates of the magnitude of biogenic VOC and NOx emissions in the various air basins of California along with comparisons of the density of anthropogenic emissions per square mile in the various basins. The information in the ARB’s 2004 Almanac includes data on man-made emissions in each basin so a simple table could be constructed to show how the emission density and population density varies across the state.

Chapter 6 Measurement of Ozone

There are several potential problems with the measurement of ozone in California as it relates to the proposed standards. The text on page 6-2 acknowledges that there are potential interferences with the UV method which is recommended as the method to determine compliance. However, Lester, Ollison, Spicer, and Satola[24] note that the UV method is prone to bias under hot humid stagnant conditions that may lead to over-reporting of as much as 20 to 40 ppb. Various states have petitioned the USEPA to address these concerns and the Agency initiated a review of the issue in 1999 but the review is not complete. Not only should the draft report acknowledge the evidence for bias, but California should actively test the state monitoring system to assure that there is no bias in the data used to determine compliance. This could be particularly important for determining compliance with the very stringent 8-hour standard in urban areas where potential interferences are more likely.

In addition to potential bias, the state should document whether the monitoring system has sufficient accuracy and precision to determine compliance with a 0.070 ppm standard. The text in Chapter 7 (page 7-9) indicates that ARB’s accuracy criteria are plus

[24] Leston, A.R., W.M. Ollison, C.W. Spicer, J. Satola, (2004), “Potential Interference Bias in Ozone Standard Compliance Monitoring,” Proceedings of the AWMA Specialty Conference, VIP-126-CD, *Symposium on Air Quality Measurement Methods and Technology 2004*, April 20-22, 2004, Research Triangle Park, NC, Air & Waste Management Association, Pittsburgh, PA. Management Association Paper, 2004

or minus 15 %. This does not appear to be consistent with a standard that would entail making distinctions between 0.070 and 0.071 ppm. Rather, the current accuracy criteria suggests that the network can only determine that a 0.070 reading is somewhere between 0.06 and 0.08 ppm. The results of the several thousand ozone audits referred to on page 7-10 should be documented and discussed in relation to the accuracy required by the proposed 8-hour standard.

Unless the possibility of bias from interferences is ruled out and the required accuracy and precision is demonstrated, the network will report false positive and false negatives.

Chapter 7 Exposure to Ozone

Section 7-4 is an analysis of potential peak exposures. The text indicates that the tables present information on the population that could be exposed to different peak ozone concentrations. However, since being inside, where people spend the bulk of their time, reduces exposure, the information presented is not meaningful or useful in estimating risk. The chance of experiencing an exposure of concern requires that the subject be outside at the location of the highest ozone and at the time of peak ozone. Finally, in order to experience an exposure that might lead to symptoms or other effects, the subject must be exercising either heavily for an hour or so or moderately for several hours or more. Since the analysis in Section 7.4 does not take these factors into account, it is not particularly relevant. Instead, the ARB should summarize the existing ozone exposure studies (both observational and model-based) that take into account the probability of being outside exercising at the time and place of peak ozone. The probabilistic exposure modeling carried out by USEPA in its 1996/1997 review is one such study.[25]

Chapter 10 Quantifying the Adverse Effects of Ozone Exposure

This Chapter was made available on August 24, 2004. We will provide comments on the Chapter by September 24, 2004. It was made clear at the August 25 2004 workshop that Chapter 10 does not represent an actual risk assessment but rather it serves as a benefit analysis of the proposed standards. Therefore, the benefits of the proposed standard are apparently based on a set of assumptions that are not necessarily borne out of a true risk assessment. It is difficult to see how staff could develop its recommendations in June 2004 without having first carried out an appropriate risk assessment. The probabilistic exposure modeling discussed above was used by the USEPA to develop its 1996/97 risk assessment before the choice of the 8-hour federal standard was made. As ARB indicates, the clinical studies of ozone exposure are the best available data upon which to base a standard. However, the 8-hour exposure protocols are not realistic so the results must be mapped onto realistic exposure scenarios to determine the actual risk from various alternative standards. As documented below, the ozone epidemiology is highly uncertain so that it cannot be relied on to assume that there will be certain benefits from the proposed standards.

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[25] U. S. Environmental Protection Agency, Review of National Ambient Air Quality Standard for Ozone: Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-96-007, June 1996.

Chapter 11 The Health Effects of Ozone Exposure

This is the key health science Chapter in the document because it presents the results of controlled exposures to ozone. The Chapter does a good job of summarizing the available data. However, there is insufficient discussion of what the data means in terms of public health. The basic database on clinical studies that is reviewed in the chapter was available to USEPA when the current 8-hour federal standard was set in 1997. The difference between the current California review and the earlier federal review as regards the clinical studies lies in the interpretation of the health significance of the information. The one area where there is important new information is on the mechanism of ozone effects. In particular, the Passannante et al. 1998 and Schelegle et al. 2001 papers provide important new information on neural mechanisms. These studies, when combined with earlier studies referenced in the chapter, lead the authors of the Chapter to conclude on page 11-8 that ozone stimulation of vagal receptors is the principal mechanism for responses such as changes in pulmonary function and respiratory symptoms.

The neural mechanism needs to be discussed throughout the Chapter and particularly as an explanation for the attenuation of responses as seen in the studies described in Section 11.4.9. The pattern of attenuation, while somewhat different from study to study, suggests that ozone responses are more dependent on the change in ozone than the absolute amount of ozone. If so, this has enormous implications for the interpretation of the clinical studies. The clinical studies are carried out with filtered air that has little or no ozone, so the studies that report effects at 0.08 ppm in exercising subjects are evaluating a change in ozone of 0.08 ppm for 8 hours. However, in the ambient air, as noted above, there is a background of ozone that averages the order of 0.04 ppm and can have maximum 8-hour concentrations in the vicinity of the proposed 0.070 ppm standard. The change in man-made ozone associated with the standard is 0.03 ppm or less not 0.07 ppm as compared to the clinical studies that evaluated a change of 0.08 ppm. If the ozone responses are dependent on the change in ozone, then the 0.08 ppm clinical studies would be representative of a 0.12 ppm ambient situation with a 0.04 ppm background. Clearly, if this were the case, the proposed standard would have a much larger margin of safety than staff thinks now.

There are several ways to test this hypothesis. One is to carry out clinical studies with realistic background ozone concentrations. Since one of the recommendations of the staff is to carry out additional clinical studies at low concentrations, studies with realistic background must be included in the protocol. To the extent that the change in ozone plays a role, the margin of safety associated with the proposed standards is larger than staff currently thinks and a somewhat higher concentration would still protect the public health with an adequate margin of safety.

Similarly, the chapter compares the FEV1 health effects at 70 ppb with health effects of 40 ppb ozone – ARB’s estimate of the concentration of background ozone. This is an appropriate comparison. However, they should have also compared reductions in FEV1 using the background level of ozone (40 ppb) compared to the clinical level of 80 ppb. The change in lung function may not have been statistically different. This is suggested by the fact that only after 5 hours of 80 ppb ozone exposure was a statistically significant effect observed. If the comparison was made against 40 ppb instead of 0.0 ppb ozone, it is likely that there may not have been any statistically significant effects.

The Chapter establishes that young adults are the most sensitive population for pulmonary function decrements and symptoms, with older adults and children being less sensitive and smokers and COPD patients being unlikely to experience marked respiratory effects. Thus, the clinical studies have identified and studied the most sensitive population for the initial physiological responses to ozone exposure, as acknowledged on page 11-211.

The recognition that neural mechanisms are involved in the respiratory and symptom effects is mentioned on page 11-144. The lack of symptoms in children is claimed to suggest a lower level of somatic awareness or impaired nociception, which might result in their failure to curtail exposure in real-life situations. However, the American Thoracic Society (ATS) guidelines upon which staff rely indicate that loss of lung function in conjunction with symptoms should be considered adverse. However, at this point in the text, the authors are arguing that lack of symptoms is itself dangerous. This is inconsistent with the ATS guideline, which is a very precautionary document.

Morphological Effects: This section (11.3) begins with a general discussion of the pattern of cellular injury and inflammatory and repair events. While there is a multitude of data showing morphological changes or other effects from prolonged exposures or repeated peak exposures (to concentrations above 0.12 ppm), the text on page 11-12 indicates that the utility of animal studies for estimating the long-term risk to human populations under ambient exposure conditions appears limited. Two reasons are given. First, concentration multiplied by time does not appear to give equal effects. The reason given is that responses may actually diminish over time. The second reason is that in the ambient, the periods when ozone is elevated to levels that can produce injury are highly variable. The text indicates that the period below threshold concentrations can vary widely. This acknowledgement that there is a threshold below which injury would not be expected to occur is very important finding and should be carried over to the summary and staff recommendation. In particular, it should be noted that long-term animal studies on exposures to near-ambient concentration, either by the National Toxicology Program (Mellick et al., 1994) or by other laboratories (Wright et al., 1988[26]), found no pulmonary lesions up to concentrations of 0.12 ppm ozone.

The discussion of the relationship between short-term effects and long-term outcomes in the summary on page 11-213 indicates that the acute responses raise concern that residual effects from repeated acute exposures could accumulate over time and could lead to chronic effects or disease. This is a concern that has been expressed for decades. There

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[26] Wright, E. S., Kehrer, J. P, White, D. M and K. L. Smiler, “Effects of Chronic Exposure to Ozone on Collagen in Rat Lung”, Toxicol. Appl. Pharmacol., **92**:445-452, 1988.

is no likelihood of large numbers of repeated peak exposures for the population at most risk. In addition, the fact that the population spends the vast bulk of its time indoors where ozone levels are suppressed needs to be taken into account when considering the possibility of chronic effects at or below the current federal standard. Since California monitors measured hourly ozone concentrations above 0.50 ppm in the 1950's, 1960's and 1970's and as high as 0.40 ppm in the early 1980's with current ambient levels still as high as up 0.20 ppm, the possibility for stronger acute effects or chronic effects in the current population is a different question.

The text on page 11-213 indicates that controlled studies do provide some guidance into the likelihood of chronic effects from ozone exposure. However, that guidance is not specified. Because both the clinical studies and the animal studies indicate thresholds, that fact should be highlighted and discussed. The text also indicates that epidemiology studies "may not always provide clear causal relationships" because of the presence of confounding factors. The text should be correlated to indicate that environmental epidemiology can not provide causal relationships.

Chapter 12 Epidemiological Studies

General Comments

In contrast to the inclusion in Chapter 11 of all the relevant studies, Chapter 12 is not a comprehensive review of all the available ozone-related epidemiology. As noted below, there are a number of relevant studies that are not included or discussed. The organization of the chapter is good, but the format of data presentation and discussion is weak. Much of the information is presented in tables, with selected results described and discussed in the text. While this works reasonably well for controlled studies, it is less than ideal for observational studies. As noted in several sections in the Chapter, statistical modeling issues are extremely important in understanding and interpreting observational studies, in general, and time-series studies, in particular. The issue of potential confounding by other environmental variables is another extremely important and subtle issue that cannot be described for a study in a few phrases or a list of pollutants studied. Finally, a listing of what the author's present as the level of ozone measured in the study is difficult to relate to the proposed standards which are extreme value 1-hour and 8-hour maxima. In the specific comments below, we provide examples of how these issues affect the interpretation of the data.

Another major concern with the chapter is the lack of overall interpretive synthesis of the information as it relates to the proposed standards. There are summary statements or paragraphs in a few sections; however, there is no systematic attempt to evaluate the overall consistency of the database. Where there are inconsistent results, there is a tendency to explain away the negative studies[27] such as the ozone was too low or the

[27] In the context of these comments, a positive study is one which reports an effect while a negative study is one which reports no effect. We also refer to positive and negative associations. In this case, a positive association is one in which an increase in pollution is statistically associated with an increase in an

sample size was too small or there was inadequate control of seasonal patterns. Examples are provided in the below discussion. In fairness, on the other hand, there are a few specific cases where positive results are discounted because of inconsistencies.

There is a discussion of modeling issues for the daily hospital admissions, emergency department visits and mortality studies. The claim is made that inadequate seasonal pattern control generally yields statistically significant inverse or negative associations between ozone and health outcomes. This is used to discount the presence of a significant number of inverse or negative associations of ozone with health endpoints in the literature, which are difficult findings to explain. The statement is made that stratification by season provides a clearer assessment of the effects of ozone. However, there are also a substantial number of negative associations when the data are stratified by season. The Health Effects Institute National Mortality and Morbidity Air Pollution Study (NMMAPS) that is described as the most robust data base on ozone mortality associations has a substantial number of negative associations. We recommend the authors of the Chapter should address questions such as how there can be such a wide variation of ozone associations both positive and negative in the data.

The city-by-city NMMAPS ozone results for <u>summer</u> are available on the author's website. They are plotted below for the association of daily mortality with same day ozone and ozone lagged 1 day and 2 days in single pollutant models, arranged in order of increasing association. The pattern of results for all three lags is the same, with a range of ozone associations from about 3 % negative per 10 ppb increase in daily ozone to 3 % positive association with a 10 ppb increase in daily ozone. The combined result for lag zero is slightly positive; it is the result included in Section 12.4. However, for the other two lags, the combined result was not significantly different from zero.

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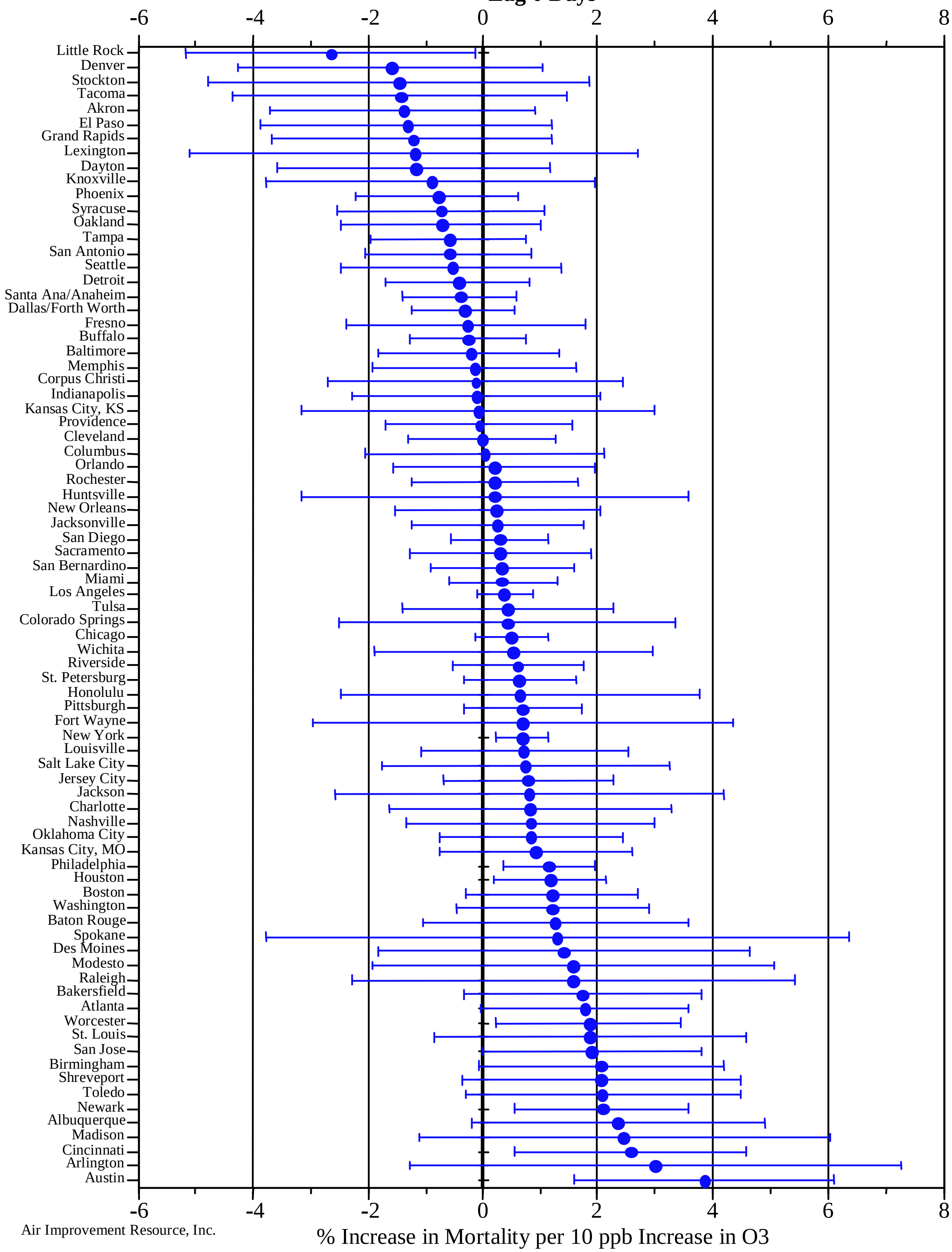
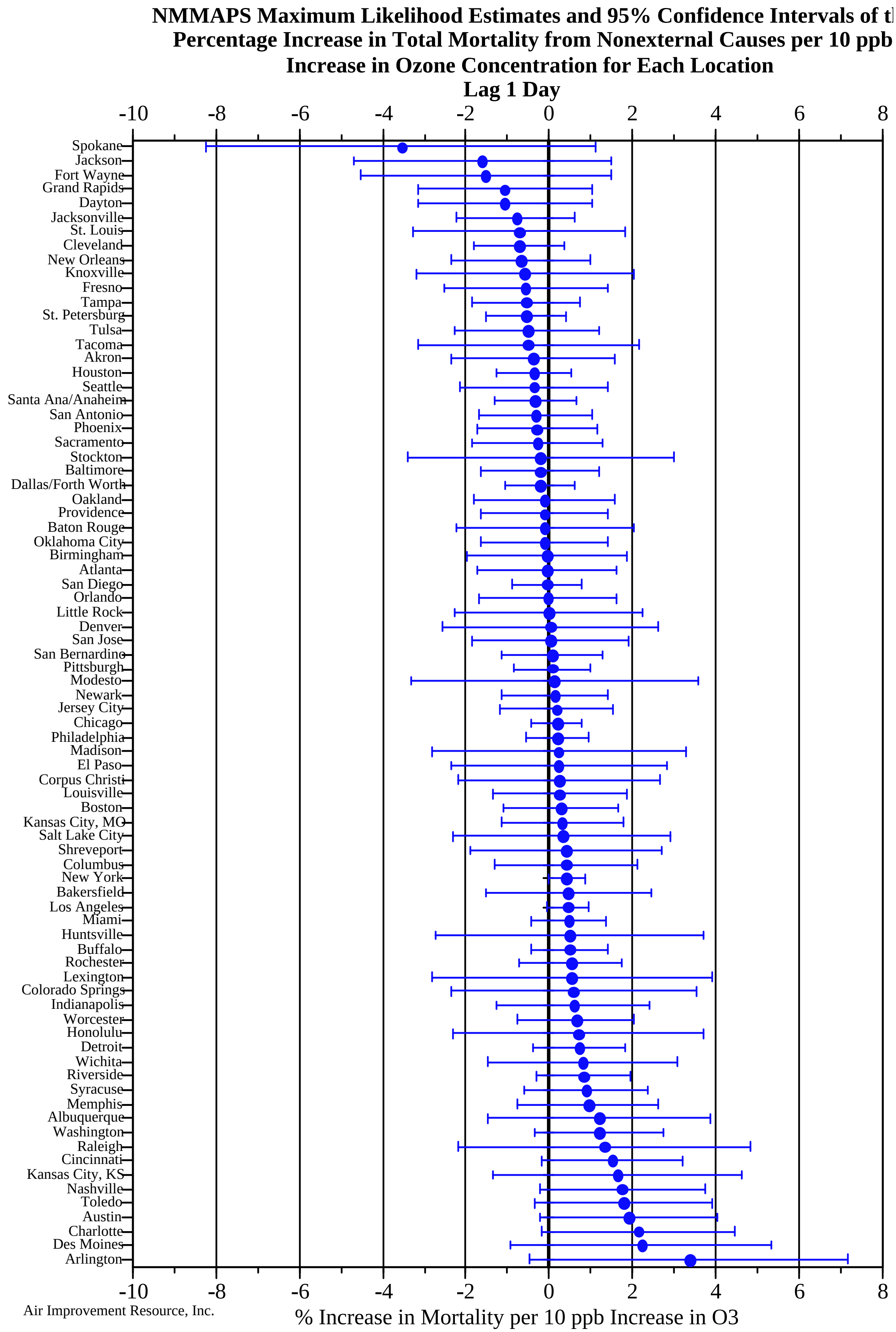
undesirable health endpoint, such as increased hospital admissions. A negative or inverse association is one in which an increase in pollution is associated with a decrease in an undesirable health endpoint.

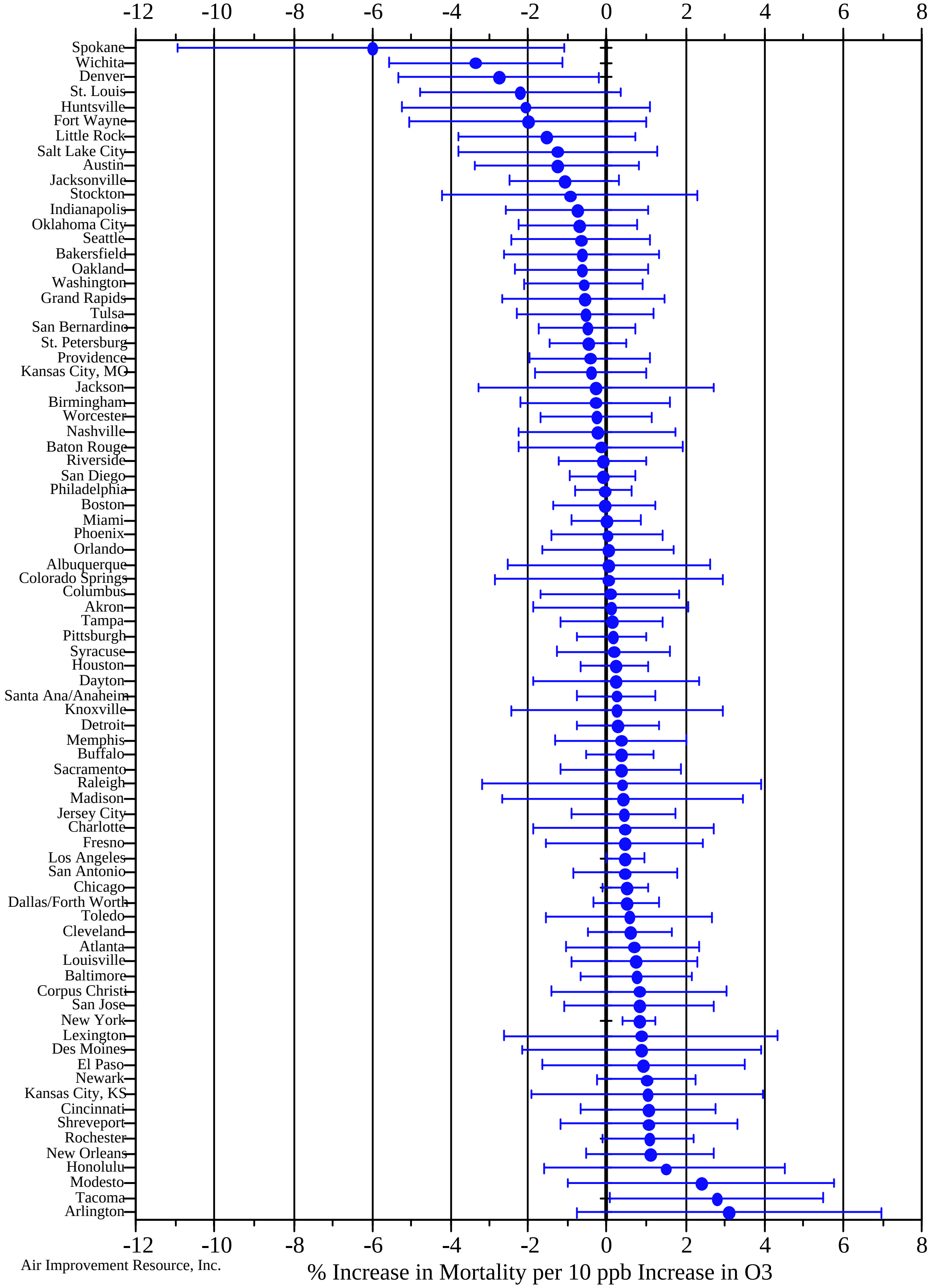
NMMAPS Maximum Likelihood Estimates and 95% Confidence Intervals of the Percentage Increase in Total Mortality from Nonexternal Causes per 10 ppb Increase in Ozone Concentration for Each Location
Lag 0 Days



Air Improvement Resource, Inc.


NMMAPS Maximum Likelihood Estimates and 95% Confidence Intervals of t
Percentage Increase in Total Mortality from Nonexternal Causes per 10 ppb
Increase in Ozone Concentration for Each Location
Lag 1 Day
-10 -8 -6 -4 -2 0 2 4 6 8
Spokane
Jackson
Fort Wayne
Grand Rapids
Dayton
Jacksonville
St. Louis
Cleveland
New Orleans
Knoxville
Fresno
Tampa
St. Petersburg
Tulsa
Tacoma
Akron
Houston
Seattle
Santa Ana/Anaheim
San Antonio
Phoenix
Sacramento
Stockton
Baltimore
Dallas/Forth Worth
Oakland
Providence
Baton Rouge
Oklahoma City
Birmingham
Atlanta
San Diego
Orlando
Little Rock
Denver
San Jose
San Bernardino
Pittsburgh
Modesto
Newark
Jersey City
Chicago
Philadelphia
Madison
El Paso
Corpus Christi
Louisville
Boston
Kansas City, MO
Salt Lake City
Shreveport
Columbus
New York
Bakersfield
Los Angeles
Miami
Huntsville
Buffalo
Rochester
Lexington
Colorado Springs
Indianapolis
Worcester
Honolulu
Detroit
Wichita
Riverside
Syracuse
Memphis
Albuquerque
Washington
Raleigh
Cincinnati
Kansas City, KS
Nashville
Toledo
Austin
Charlotte
Des Moines
Arlington
Air Improvement Resource, Inc.
% Increase in Mortality per 10 ppb Increase in O3

NMMAPS Maximum Likelihood Estimates and 95% Confidence Intervals of t Percentage Increase in Total Mortality from Nonexternal Causes per 10 ppb Increase in Ozone Concentration for Each Location
Lag 2 Days



Air Improvement Resource, Inc.

Ozone is the only pollutant for which NMMAPS seasonal results have been published to date. The NMMAPS database is particularly important because, by including all the 90 largest U. S. cities with data, it avoids the issue of publication bias. The wide range of ozone associations in the data, using the same methodology, demonstrates the inherent noise or variability in the data. The same wide pattern of associations ranging from strongly positive to strongly negative is observed in the individual NMMAPS data for all the pollutants studied at all the lags studied.[28] The combined winter ozone-mortality association was slightly negative and so many negative as well as positive associations are presumably present in that data. We encourage ARB staff to revaluate the winter ozone data when available.

A comparison of the wide range of positive and negative associations in the robust NMMAPS data set compared to a truncated range of associations in the published literature as summarized by Stieb et al.[29] leads us to suggest that publication bias is a major issue in the air pollution epidemiology literature. Since the Chapter discusses several forms of bias in the data, the issue of publication bias needs to be added to the list.

As indicated on page 12-67, the growing literature on acute ozone effects is related to the exploding interest in acute PM effects. We disagree, however, that ozone is treated just as a confounder in many multi-pollutant studies. Many investigators have taken the full suite of pollutants available in a given location and evaluated each in single pollutant models. Whatever the results of the analysis, the positive associations were stressed in the publications. If ozone happened to have no association or a negative association, that was included in the paper but, for obvious reasons, not highlighted. In contrast, in studies that focus on ozone, it is not likely that negative associations would be published.

As the burgeoning PM literature has been reviewed by USEPA, we and others have raised issues regarding publication bias, single pollutant model bias, reporting of best lags bias, and the reviewing agency's selection bias. Each of these biases is a potential concern in the ozone epidemiology as well and should be discussed in the Chapter.

Field Studies of Acute Respiratory Effects

Lung Function Although there are several studies that report lung function effects, the data is mixed. In particular, there are several studies in California that report little or no effects. The Delfino study of asthmatics in Alpine and the Linn study in Rubidoux, Upland and Torrance are noted in the text and are of particular import. Although, the author tries to rationalize why no effects were seen, the possibility that no effects were present is not one of the possibilities considered. This possibility should be discussed

[28] J. M. Heuss and J. J. Vostal, Comments on the Fourth External Review Draft of "Air Quality Criteria for Particulate Matter" EPA 600/P-99/002aD, June 2003, Prepared for General Motors Corporation. August 28, 2003.
[29] Stieb et al., J. Air & Waste Management Association, **52**, 470-484, 2002; Stieb et al., J. Air & Waste Management Association, **53**, 258-261, 2003.

Related to this, the description of ozone levels in Rubidoux and Upland as quite low is discussed as a potential reason for a no effect finding. Additionally, the description of the Neas study in Philadelphia, which omits the comment in the table that the ozone results were not robust to the inclusion of sulfate in the model, is another example. The Mexico City study in which the ozone effect became non-significant with fine PM in the model is mentioned but the high ozone levels noted in the table are not given.

There is a particularly important study of asthmatic and healthy children in Southern California that is not mentioned in the chapter. The Health Effects Institute study by Avol et al.[30] evaluated potential acute respiratory effects of ambient ozone in the spring and the summer. About 200 ten to twelve-year old children from Lancaster, San Dimas, Upland, Mira Loma, Riverside and Lake Arrowhead were studied in the spring and late summer of 1994 with monitored hourly ozone levels exceeding the federal 1-hour standard in each season and with peak hourly levels up to 200 ppb in the summer period.

There was no discernible pattern of diurnal lung function changes by season, by ozone level, or by health group. While there were individual improvements and decrements in lung function observed, there was a general tendency for improvement and not reductions in lung function.

There was also no consistent or clear role of ozone in producing changes in reported symptoms or medication use. There were increased symptoms and medication use on high ozone spring days but not high ozone summer days. The spring results may have occurred because the subjects were more sensitive in the spring or, as the HEI Review Committee suggests, a result of enhanced response to allergens from springtime pollen blooms. The review committee also noted that there was an increased frequency of inhaler use on low ozone days in the summer but not on high ozone days.

The authors note that the failure to detect clear evidence of acute pulmonary effects in the three groups may be due to the fact that ozone levels were not sufficiently elevated during the study, although they exceeded 80 ppb during the study. The authors note that the children in their study, on average, did not spend the time exercising at the high levels used in the chamber studies.

The Chapter should include the HEI study and integrate it into a discussion of all the field studies of acute respiratory effects in California.

The Brauer study is highlighted in the text. However, possible confounding of ozone effects with coarse PM or coarse bioaerosols is not mentioned. In any case, the interpretation of the lung function effects for these heavily exercising outdoor workers needs to include consideration of the neural mechanism. Although there was an attempt to gather symptom data for these workers, no symptom results are given in the paper.

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[30] E. Avol, et al., Acute effects of ambient ozone on asthmatics, wheezy, and healthy children, Health Effects Institute Report Number 82, 1998.

Symptoms The results for respiratory symptoms are also mixed. The text acknowledges that there are several studies of respiratory symptoms in California that failed to detect symptom effects. The HEI study (Ayol et al.) should be discussed in this section, too. We note the Mexico City results do not discuss the levels of ozone or other pollutants during the studies.

The interpretation of symptom studies also needs to consider the neural mechanism. The adaptive inflammatory response is noted in the discussion of the Kopp study. Since other pollutants are now thought to contribute to inflammatory responses, the possibility for confounding by other pollutants needs to be considered when evaluating inflammatory endpoints.

Other Respiratory Effects On balance, there is very little evidence pointing to inflammatory effects related specifically to ozone in real-world populations. In addition, as noted above, there is limited evidence for lung function changes and symptoms. The Gilliland study of school absences is important but it is the only study of its type. As noted in the text and the table, there is a question of residual seasonal confounding for this study. A counterintuitive result that raises additional questions is that the reported effect is substantially larger in the low ozone communities compared to the high ozone communities. Potential confounding by bioaerosols was not evaluated in the study. It would be particularly important to replicate the study in another cohort and over all seasons. The many issues with model selection that have arisen in recent years raise additional concerns that the result may not be robust. The large reported ozone effect on respiratory absences seems out of proportion to the lack of substantial effects on respiratory symptoms seen in school children in the Basin. In any case, interpretation of all these studies in relation to the proposed standard needs to consider that the exposures in urban and suburban areas are significantly above those that would occur upon attainment of the proposed standards.

Daily Hospital Admissions and Emergency Department Visits

Hospital Admissions This section of Chapter 12 discusses many issues related to the conduct and interpretation of time series studies. As noted above in general comments on the chapter, inadequate control for seasonal confounding cannot be the explanation for all the negative or inverse ozone associations in the literature.

The text in this section discusses several studies with positive findings at length but only in passing notes that there are negative findings from several studies in the LA Basin. Because of the relevance of California studies to setting California air quality standards, all the available California studies should be discussed and compared. Linn et al., 2000 report an analysis of associations between CO, NO_2, PM10, and ozone with hospital admissions for cardiopulmonary illnesses in metropolitan Los Angeles. They report that CO showed the most consistent relation to cardiovascular admissions, but that:

> "NO_2, and, to a lesser extent, PM10 tracked CO and showed similar associations with cardiovascular disease, but ozone was negatively and nonsignificantly associated."

In addition, pulmonary disease admissions associated more with NO_2 and PM10 than with CO. Pulmonary effects were generally smaller than cardiovascular effects and more sensitive to the choice of model. They concluded that high primary pollution most common in autumn/winter increases the risk of hospitalization but that summer photochemical pollution presents less risk.

Nauenberg and Basu 1999 evaluated associations between asthma-related hospital admissions and exposure to PM10 and ozone. They found no association between asthma and ozone even when seasonal analyses were performed.

Van Den Eden et al.[31] carried out a study of hospital admissions in the Central Valley using the GAM approach. Ozone had a negative association; that is, it was associated with a decreased risk of both acute respiratory and chronic respiratory admissions.

While GAM studies, in general, are suspect, it is not clear whether their results for ozone will be substantially altered by re-analysis. Since studies such as the Van Den Eden studies have been carried out in the high pollution areas of California, they should definitely be re-analyzed to aid in the understanding of health effects in California.

Other studies with less robust or negative findings are dismissed in the review because they used case-control methodology (Lin) or are difficult to interpret because of the large number of statistical tests performed (Schouten). These do not appear to be valid reasons for dismissing studies. The authors should elaborate on their concerns to enable the reader to judge their merit.

The distinction in the review between studies with five or more years of data and those with less is not relevant. The statistical power depends on the number of events which in turn depends on the size of the population under study and the prevalence of the event as well as on the length of data record.

Heavy reliance is placed on the Burnett (Canadian) and Anderson (European) multi-city studies. However, as shown in the NMMAPS analyses, the range of individual city results in multi-city analyses with a consistent methodology is very large and not biologically plausible. Combining results that are not biologically plausible may give an overall association, but it may just represent residual confounding. The wide range also indicates that individual city studies are not reliable. This is supported by the fact that "alternative analyses of data from the same city sometimes resulted in differing results" (page 12-76). There are, in fact, many examples in the literature of this phenomenon. It is a practical example of the model selection issue that has been raised in the federal PM review based on the HEI Special report on re-analysis of time-series studies. The Health

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[31] Van Den Eden et al., 2002, Central Valley hospital admissions study for ARB, Final Report ARB Contract 97-303.

Effects Institute Special Panel[32] that reviewed the re-analyses concluded that "neither the appropriate degree of control for time in these time-series analyses, nor the appropriate specification of the effects of weather, has been determined." They went on to indicate that "this awareness introduces an element of uncertainty into the time-series studies that has not been widely appreciated previously."

Given the many issues raised by the author in Section 12.2.1 as well as other issues raised in these comments, the only conclusion that can be drawn is that while there are many positive ozone associations with hospital admissions in the literature, individual city studies are not reliable due to model selection issues and multi-city studies are suspect, too. This conclusion may be considered controversial. However, many competent investigators are becoming more skeptical about the interpretation of weak air pollution associations.

For example, Moolgavkar has expressed severe reservations. He published several studies of hospital admissions in Los Angeles using GAM but did not include ozone in the suite of pollutants he considered. In one of his studies, Moolgavkar 2000, he noted discrepancies between his findings and that of other studies of hospital admissions in Los Angeles. He acknowledged that he did not know how to explain the discrepancies. Although there were differences in the methods of analysis, he didn't think they could explain the discrepancies. However, he went on to indicate:

> "If indeed they do, then one must conclude that results of time series analyses can be quite sensitive to statistical approaches."

In the re-analysis of his results in 2003, he found some findings changed and some did not. Based on his results and those of other investigators, he concluded that "given that different analytical strategies can substantially affect the estimates of effects of individual pollutants, I believe that no numerical estimates are very meaningful."[33]

Vedal and co-workers[34] have also expressed the concern that pollutant/health associations may not be effects of the pollutants themselves, but rather of some other factors present in the air pollution-meteorology mix.

In addition, Lumley and Sheppard[35] point out that "estimation of very weak associations in the presence of measurement error and strong confounding is inherently challenging. Prudent epidemiologists should recognize that residual bias can dominate their results."

The current practice of using central station monitoring data, central station weather data, and available health statistics yields many weak positive associations for various pollutants. However, it is known that the methodology is subject to problems of

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[32] Health Effects Institute, Special Report: Revised Analyses of Time-Series Studies of Air Pollution and Health, May 5, 2003.
[33] S. Moolgavkar, in Health Effects Institute, Special Report: Revised Analyses of Time-Series Studies of Air Pollution and Health, May 5, 2003, page 198.
[34] S. Vedal et al., Environmental Health Perspectives, **111**, 45-51, 2003.
[35] T. Lumley and L. Sheppard, Epidemiology, **14**, 13-14, 2003.

measurement error and exposure miss-classification as well as severe collinearity between weather and pollution variables. When the uncertainty due to model selection issues is added, and the potential biases noted above are considered, the interpretation of a subset of positive findings as causal becomes problematic.

Emergency Department Visits The text indicates that, if hospital admissions are affected by ozone, then it is likely that ED visits would also be affected, and to a greater degree. However, the text also acknowledges that the ED results are less consistent, with effects apparent only in selected sub-groups and at certain lags. The text goes on to state that for 20 studies with adequate seasonal controls, 16 reported at least one significant association involving ozone. Given the strong views portrayed in the review as to what constitutes adequate seasonal control, the selection criterion for the 20 studies should be spelled out. Given that studies without effects are difficult to publish and that these studies often include multiple comparisons, it is not surprising that there would be a number of positive associations in the literature. However, if as acknowledged, there is no clear pattern of association with specific respiratory disease outcomes, it is hard to accept this data as evidence of effects.

The review focuses on a subset of studies that evaluated dose-response within the set of studies that evaluated ED visits for asthma. However, a significant number of other studies in the set are discussed as showing no effects or inconsistent effects or are noted as not interpretable. Although the Hajat et al. 2002 study is discussed in the chapter, the Hajat et al. 1999[36] study of the relationship between daily general practitioner consultations for asthma and other lower respiratory diseases with air pollution in London is omitted. Hajat et al. 1999 report that a consistently negative association with ozone was observed in both disease categories. Hajat et al. 1999 also evaluated seasonal models. In addition, the Sunyer et al. 1997[37] study of emergency admissions for asthma in four European cities is omitted. They report the association between asthma admissions and ozone for adults was heterogeneous among cities. For children, they report no association was observed for ozone. They also carried out seasonal analyses but found no consistent results for ozone. With some studies omitted and many others set aside, it is not clear how representative the subset of studies chosen for further analysis actually is. Since the studies included in the tables are only a selected subset of all the studies in a given area, one cannot rely on the table to estimate how consistent the literature is for a given health endpoint.

Among the subset of studies that evaluated dose-response, an apparent threshold was identified. Given that the overall data on asthma ED visits is highly variable and inconsistent, the asthma data can, at best, be viewed as suggestive.

The issue whether reported ozone effects are specific to ozone is important. The text list several hospital admissions studies that reported ozone associations that were robust to inclusion of co-pollutants. This is not a sufficient basis for drawing the conclusion that the evidence is fairly supportive of independent effects. There is no discussion of studies

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[36] S. Hajat et al., Thorax, **54**, 597-605, 1999.
[37] J. Sunyer et al., Thorax, **52**, 760-765, 1997.

that reported differently or reported no association in the first place. For asthma, bioaerosols are a prime candidate as independent causal agents, but they are not measured in most studies.

Respiratory Effects of Long Term Exposures

This section is introduced by quoting the USEPA that there was only suggestive evidence in 1996 of health effects from chronic ozone exposures. The literature reviewed in this section does not change that conclusion. There is little evidence of respiratory inflammation specific to ozone. There is inconsistent and inconclusive evidence of increased mortality risk. There are several studies that report no associations of asthma prevalence, asthma symptoms, and self-reports of respiratory symptoms or asthma. While there are some reports of seasonal lung function changes, they should be interpreted in light of the neural mechanism as well as the findings from Gauderman 2000 that decrements in lung function growth were not related to ozone.

The McConnell 2002 finding of an association of ozone in high ozone communities with new on-set asthma in children that played three or more sports is important. The number of cases was small. As the text indicates, replication would lend greater weight to a causal interpretation. However, the effect was observed only in the high ozone communities; in the low ozone communities, there was no effect. In addition, the effect was restricted to a small subset of the cohort; overall, there was no increased asthma risk in the high ozone communities. The low ozone communities had low ozone in the context of Southern California ozone levels, which are the highest in the nation. The peak levels measured in the low ozone communities, where there was no effect of new on-set asthma are above the proposed standards.

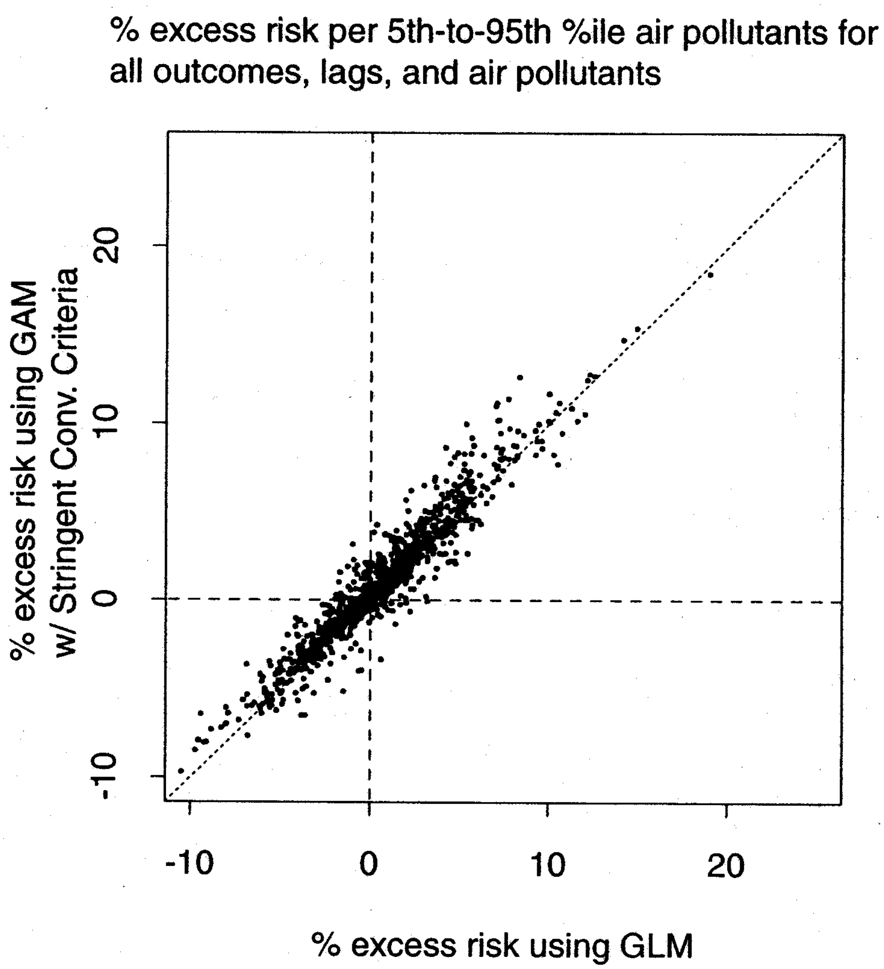
Given that Southern California has had elevated ozone levels for over 50 years, with peak 1-hour levels in the past as high as 700 ppb and current peak 1-hour levels in the range of 200 ppb, it is remarkable that there is only suggestive evidence for chronic ozone effects. Apparently, the respiratory system has effective defense mechanisms. We recommend a broader discussion of this in the next draft of the review document. Although ozone is an irritating gas, the presence of a significant background of ozone together with the fact that ozone exposures are suppressed indoors where people spend much of their time probably play a role in the minimal number of demonstrable long term effects to date.

Acute Mortality

As discussed above, there are many issues with time series studies. This section of Chapter 12 discusses several of the issues and limitations but goes on to develop an estimate of an ozone/mortality effect in the summer. As demonstrated above, there is a wide range of associations from positive to negative in the NMMAPS 90-city summer ozone data in single pollutant models. As shown in figure 12-2, <u>none</u> of the combined associations in multi-pollutant models were statistically significant.

While there are some inverse or negative air pollution associations reported in the literature, the NMMAPS study shows that there are many more negative associations in the data than in the literature. When the GAM issue was raised and many time series studies were re-analyzed, Ito[38] systematically re-analyzed the 1220 separate air pollution mortality and morbidity associations that were included in the original Lippmann et al. 2000 HEI study of Detroit. As shown below, there was a wide range of negative and positive risks in Detroit when all pollutants, lags, and endpoints were considered. Ito showed in separate figures that the wide range of associations occurred for each pollutant. Although the focus in the original Lippmann study, as it is in almost all the published literature, was on the positive associations, Ito's plot shows that there are many negative associations in the data. Although there may be somewhat more positive associations than negative associations, there is so much noise or variability in the data, that identifying which positive associations may be real health effects and which are not is beyond the capability of current methods.

[38] K. Ito, in Health Effects Institute, Special Report: Revised Analyses of Time-Series Studies of Air Pollution and Health, May 5, 2003.



Another important systematic analysis was carried out by Koop and Tole 2004[39] using the Bayesian model averaging to evaluate model uncertainty in time series analyses using an extensive set of pollutant and meteorological variables from Toronto, Canada. They summarize their results as follows:

> "Point estimates of the effect of numerous air pollutants all tend to be positive, albeit small. However, when model uncertainty is accounted for in the analysis,

[39] G. Koop and L. Tole, J. of Environmental Economics and Management, **47**, pages 30-54, 2004.

> measures of uncertainty associated with these point estimates became very large. Indeed they became so large that the hypothesis that air pollution has no effect on mortality is not implausible. On the basis of these results, we recommend against the use of point estimates from time series data to set regulatory standards for air pollution exposure."

Importantly, the authors demonstrate that the results of a single model based on a sequence of hypothesis tests will overestimate the certainty of the results. This is not a new finding in the statistical literature but it has not been carefully considered in the air pollution literature. They use an example to show how the results of a single regression "may lead researchers to make misleading inferences about pollution-mortality effects, thereby seriously underestimating the true uncertainty in the statistical evidence."

As noted above, the HEI Special Panel also concluded that model selection issues such as specification of weather and degree of control for time "introduce an element of uncertainty that has not been widely appreciated previously." In fact, the Koop and Tole analysis is the kind of analysis the Panel recommended to investigate the sensitivity of results to model selection issues. By rigorously evaluating the uncertainty with Bayesian model averaging, they show that there is much greater uncertainty in the time series studies than commonly reported.

Koop and Tole, as noted above, show that individual model results are unreliable. In comments on the federal PM Criteria Document, AIR has presented evidence[40] that led us to same conclusion. By empirically comparing the results of different time series studies of the same city by different investigators, we showed that the results change, often substantively. Subtle differences in model selection can shift the strength of association with a given pollutant, can change the pollutant or pollutants implicated by a given study, and can change the health endpoints that are supposedly affected by the pollutant or pollutants. We applaud the Chapter authors for making the Chapter makes the same general point on page 12-76. There are, however, many more examples in the literature than ARB indicates.

Since model uncertainty is greater than generally appreciated, evidence exists for several major biases in the data in the literature, and systematic studies do not implicate ozone any more than any other pollutant, there is little value in attempting to derive an ozone mortality association. As ARB and OEHHA review the air quality standards for each pollutant in turn, there is some evidence in the literature to implicate that pollutant in premature mortality. The text spends a great deal of time discussing the warm season ozone association. However, the Stieb et al. meta-analysis showed that warm season associations are stronger than cold season associations for other pollutants, so ozone is not unique in that respect.

Instead of concentrating on the studies in the literature that report positive associations, the authors of the Chapter should address questions such as how there can be such a wide variation of ozone associations both positive and negative in the data. It is not

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[40] See AIR, Inc. comments on 2nd, 3rd, and 4th drafts USEPA PM Criteria Document.

biologically plausible that ozone would be causing mortality in some cities in the summer and protecting against mortality in others.

The text indicates that the range of ozone mortality estimates is relatively narrow with 27 of 33 studies being between 0 and 6.6 % per 40 ppb increase in 1-hour maximum ozone. **[**However, the full range of studies in Figures 12-3 and 12-4 is more like -5 to + 15 %. Even this is misleading, because the Figures presents the combined result for NMMAPS rather than the individual city results which, for summer, varied from – 12 % to + 12 %. This wide a range is not biologically plausible. The authors of the strongest association, Vedal et al. 2003, highly qualify their results noting that they are not biologically plausible and that ozone may be acting as a surrogate for something else in the meteorology-air pollution mix.

Another factor noted in the text that should be considered is the lack of a mortality signal such as the 1952 London episode. The lack of a strong health effects signal from the extremely high ozone concentrations measured in Southern California in the 1950's and 1960's argues against a causal ozone mortality association. The Chapter suggests that a 40 ppb change in 1-hour ozone causes a 3 % increase in mortality, and literature suggests that at even larger increases in ozone the mortality signal in the 1950's and 1960's with 500 ppb 1-hour ozone concentrations would have been too large to miss. In addition, the clinical studies suggest that there are thresholds for the first effects, which are neurally mediated, that, according the USEPA exposure analysis, are not exceeded for the majority of the population the majority of the time, even at current ozone levels.

The text discusses confounding and presents the results of selected studies of ozone with and without PM indices in Figure 12-5. The statement is made that, in general, PM did not affect the ozone mortality risk estimates except in Los Angles and Mexico City. However, these two cities are known to experience very high ozone levels compared to other cities around the world. In addition, PM is not the only potential confounder. In the Stieb et al.[41] meta-analysis, a more comprehensive analysis of multi-pollutant models including ozone was reported. The combined ozone association from single pollutant models was reduced and became non-significant in multi-pollutant models. In the NMMAPS summer ozone analyses, the combined result from the 90-city study was not significant in any of the multi-pollutant models, as shown in Figure 12-2.

Given the many limitations in the mortality analyses that the authors discuss, the greater than previously appreciated uncertainty due to model selection issues, and the bias due to reliance on single pollutant models, the preliminary conclusion that ozone represents an independent risk factor for premature mortality cannot be supported. The Chapter should be revised to fully acknowledge the limitations of time series analyses and the growing skepticism in the technical community as to its usefulness.

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[41] Stieb et al., J. Air & Waste Management Association, **52**, 470-484, 2002; Stieb et al., J. Air & Waste Management Association, **53**, 258-261, 2003.

Chapter 8 Staff Recommendation for Standard

The staff recommendation begins with an exposition of five factors that were considered when ARB and OEHHA determined that a thorough review of the ozone standard was necessary. The five factors were:

1. The extent of the evidence of effects reported to occur at or near the existing ambient air quality standard
2. The nature and severity of those effects
3. The magnitude of risks of effects anticipated when ambient (outdoor) levels are at or near the level of the existing standard
4. Any evidence indicating that children may be more susceptible to effects than adults, and
5. The degree of outdoor exposure in California relative to the level of the standard.

We concur that the first four of these items must be considered when addressing the protectiveness of the standard, but are unclear about the fifth item. If by degree of outdoor exposure, staff means the amount of time that outdoor levels approach the standard, we note that this is necessary, but not sufficient to would argue determine the risk. The magnitude of risks of effects depends on the personal exposure of California residents, not just the ambient levels themselves. Personal exposures depend on both ambient levels and activity patterns. Unless activity patterns and the full range of personal exposures are considered, the magnitude of the risks and, therefore, the public health implications of alternative standards cannot be accurately evaluated. The draft staff report does not attempt to evaluate the distribution of personal exposures that would occur upon attainment of the proposed standards. We recommend this analysis be incorporated.

In addition, the staff recommendation does not adequately consider and evaluate three (#2, 3, and 5) of the five factors. While Chapter 11 adequately reflects literature from clinical studies, Chapter 12 and the staff recommendation overstate the extent and consistency of the epidemiologic evidence. The discussion of the nature of the clinical effects is incomplete without considering the implications of the neural mechanism of lung function test decrements and symptoms. There is little or no discussion of the severity or medical significance of the clinical effects. Reference to the American Thoracic Society (ATS) guidelines is an appropriate first step in evaluating the effects, but it does not substitute for a more focused and detailed discussion of the medical significance of isolated, transient, and reversible effects due to ozone. Lastly there is no discussion of the frequency of occurrence of personal exposures at potential levels of concern.

These deficiencies must be corrected before an appropriate standard to protect the public health is determined. In contrast, the USEPA went through a more thorough process in setting the current 8-hour federal standard. We recommend that ARB/OEHHA go through a similar process. Federally, the nature and severity of effects was discussed at length by CASAC and USEPA staff and summarized in a Staff Paper[42] that was acceptable to CASAC. A range of possible standards was evaluated with a probabilistic national exposure model.[43] Based on these analyses, the Committee as well as various individual CASAC members offered their advice to the Administrator as to a standard that would protect the public health with an adequate margin of safety.

We note that the standard finally promulgated by the Administrator allows both a higher 8-hour concentration than the California proposal as well as more exceedances in a year. When the California proposal is expressed in the same statistical form as the federal 8-hour, 0.08 ppm standard, it is equivalent to about 0.063 ppm. However, there is no information provided on why the interpretation of the science is so different between EPA and ARB. We recommend ARB Staff collaborate with their counterparts at the U.S. EPA in order to establish a common understanding of the science, to provide for a comprehensive explanation of any differences in interpretation of the science, and to reconcile legitimate differences and questions through further research if necessary. We consider it likely that through exploring such differences in interpretation of the science will assist ARB in setting a standard based on sound science and will serve to abate some of the concerns of our industry and other interested stakeholders.

Basis for the ARB/OEHHA Recommendation

The staff recommendation (Chapter 8 and Appendix B) starts with a presentation of the American Thoracic Society (ATS) guidelines for adverse effects. The findings from controlled chamber studies are then reviewed and the text indicates that many health outcomes from chamber studies could be considered adverse. Several reasons are given for choosing the proposed standards and the margin of safety associated with them.

Comments on the Margin of Safety in the Staff Recommendation

As noted above, several reasons are given by staff for choosing the proposed standards and the margin of safety associated with them. First, it is indicated that the proposed standards are somewhat below the lowest levels reported where statistically significant group mean decrements in lung function were observed. Thus, there is margin of safety in the concentration recommended for the standard. However, there is no discussion of the statistical form for the standard which is recommended as a concentration not to be exceeded. This extreme value form, in itself, adds a substantial margin of safety in that it drastically limits the number of potential repeat exposures. The USEPA exposure and risk analysis demonstrates that there will be a minimal number of days of ozone-related respiratory effects with 8-hour concentrations up to 0.09 ppm and employing much more robust statistical forms allowing up to 5 exceedances per year.

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[42] U. S. Environmental Protection Agency, Review of National Ambient Air Quality Standard for Ozone: Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-96-007, June 1996.
[43] See USEPA Staff Paper at pages 73-101 for description of the national exposure model and pages 104-129 for description of the risk assessment.

Second, it is indicated that a margin of safety is needed due to variability in human responses especially the existence of particularly large individual responses of FEV1. However, reconsideration of the clinical significance of the variability is warranted given the recent information available on the neural mechanism responsible for the responses.

Third, concern is expressed over chamber studies indicating, at higher ozone levels, pulmonary inflammation. The discussion of the 1-hour standard notes that bronchial responsiveness and pulmonary inflammation occur at 0.18 to 0.20 ppm in chamber studies, but this only occurs with heavy exercise. While the staff acknowledges that the ultimate impact of the inflammatory response is unclear, the clinical significance of single, acute mild inflammatory changes is not discussed in the report. The USEPA risk analysis[44] shows that there will not be a pattern of repeated exposures leading to inflammatory changes at alternative standards that are higher than the staff recommendation.

Fourth, the concern that animal studies suggest the possibility of decreases in lung defense mechanisms is raised. However, Chapter 11 acknowledges the limited value of animal studies and the existence of a threshold in the injury and repair phenomenon.

Fifth, reference is made to epidemiologic studies reporting associations with a wide range of health outcomes up to and including premature mortality. However, as discussed in detail in the comments on Chapter 12, there is much more uncertainty and much less consistency in the epidemiology than discussed in the draft report.

Sixth, it is indicated that the chamber studies do not include especially vulnerable populations. However, Chapter 11 and the staff recommendation both indicate that the chamber studies do capture the effects in the population most at risk, which are those who spend prolonged periods of time outdoors while participating in some activity that increases the breathing rate. This group is comprised primarily of children, outdoor workers, and recreational/amateur/professional athletes. (Pages 11-210 and 11-211)

Seventh, while it is acknowledged that the ultimate impact of the inflammatory response is unclear, concern is expressed that repeated exposure to high ozone concentrations may result in restructuring of the airways, fibrosis, and possibly permanent respiratory injury. In addition, it is indicated that a large margin of safety may be necessary to account for the possibility of adverse long-term impacts. Since the USEPA risk analysis demonstrates that repeat exposures of concern are minimal at even higher alternative standards, this concern is primarily speculation. The lack of a clear chronic respiratory signal due to ozone in Southern California despite the high ozone exposures that have historically occurred there argues against the possibility of adverse long term impacts at or even close to the proposed standards. Therefore, a large margin of safety is not necessarily required to guard against potential long-term impacts.

Eighth, staff indicates that a concentration of 0.08 for an 8-hour standard is not sufficiently protective of public health because of a substantial fraction of subjects in the

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[44] See USEPA Staff Paper at pages 104-129.

8-hour studies with particularly marked responses in lung function and symptoms. Staff indicates that 0.070 ppm, not to be exceeded was recommended to ensure a minimal number of days of ozone-related significant respiratory effects for children and adults. However, ARB/OEHHA did not carry out an exposure/risk assessment to determine the risk to children or outdoor workers from alternative standards.

The ARB has sponsored research projects[45] on the activity patterns of adults, adolescents and children. The ARB gathered this data because reducing the health risk of children and others "requires accurate estimates of exposure to pollutants." The Children's Health Study and the HEI study of asthmatic, wheezy and healthy children collected data on activity and exertion levels. These studies show that children in California spend about 10 or 11 percent of their time outdoors, with mean time outdoors and active of about two hours. In order to understand the risk from alternative standard levels, ARB should use this information to determine the distribution of personal exposures and activity levels under its proposed standards as well as under alternative standards. Without such information, it is impossible to make an informed judgement about a standard designed to "ensure a minimal number of days of ozone-related significant respiratory effects for children and adults." The USEPA carried out an exposure and risk analysis that demonstrates that there will be a minimal number of days of ozone-related respiratory effects with 8-hour concentrations up to 0.09 ppm and with more robust statistical forms allowing up to 5 exceedances per year.

Outcome of the Federal Review

When the USEPA and its scientific advisors, the Clean Air Scientific Advisory Committee, evaluated the health effects of ozone, the process was much more involved and resulted in very different conclusions. The USEPA reviewed the same basic body of information on controlled exposures to ozone. The federal process involved the preparation and CASAC review of a several hundred page Staff Paper. The final Staff Paper basically agrees with the OEHHA staff concerning the concentrations and duration of exposure where the first effects are seen.[46] For example, EPA staff concluded that the lowest range within which 1- to 3-hour exposures to ozone at heavy exertion produce group mean statistically significant lung function decrements is 0.12 to 0.16 ppm. They concluded that the lowest range for 6- to 8-hour exposures at moderate exertion is 0.08 to 0.12 ppm. For respiratory symptoms, the USEPA staff concluded that the lowest range for 1- to 3-hour exposures at heavy exertion is 0.16 to 0.18 ppm and for 6-to 8-hour exposures at moderate exertion, it is 0.08 to 0.12 ppm. For biochemical indicators of pulmonary inflammation, the lowest level for short-term exposures was noted as 0.20 ppm and the lowest level for 6- to 8-hour exposures was 0.08 to 0.10 ppm. These findings are remarkably similar to those from the California review.

Where the federal review differs is in the examination and consideration of how these findings should affect the standard and its required margin of safety. USEPA staff indicated that it is important to consider the extent to which at-risk groups are likely to be

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[45] ARB Research Note 94-6, April 1994
[46] See USEPA Staff Paper at pages149-150.

exposed to ambient concentrations associated with such effects, the mechanisms by which the effects occur, and the resulting risk of experiencing these effects. To evaluate these issues, USEPA staff undertook two detailed efforts beyond those carried out by OEHHA staff.

First, EPA staff and CASAC spent a considerable amount of time evaluating the current understanding and divergence of opinion in the scientific community as to what respiratory effects and degrees of response might be regarded as adverse health effects associated with ozone.[47] They considered asthmatic and health individuals and categorized the various functional and symptomatic responses. Based on discussions with medical experts who have worked with asthmatics, staff concluded that single ozone exposures that resulted in moderate responses are not likely to interfere with normal activity nor to result in increased frequency of medication or the use of additional medications. However, staff felt that moderate exposures when repeated could result in an increased likelihood of many asthmatic individuals to limit normal activity. Therefore, they recommended that moderate symptom and functional responses, when repeated, should be considered as adverse health effects. For healthy individuals, there was a consistency of CASAC opinion that single, acute moderate health responses should not be considered adverse. Because of concern over repeated health effects, staff recommended that the number of ozone exposures resulting in moderate health effects should be considered as a factor in characterizing the adversity. The section of the USEPA staff report discussing these judgements is 14 pages long, in contrast to the limited discussion in the OEHHA staff recommendation.

Second, USEPA staff undertook an extensive exposure and risk analysis with input from CASAC. The analysis which is documented in the Staff Paper was very conservative in that it assumed lung function decrements started at 0.04 ppm, assumed no attenuation of effects, assumed that that children experienced the same level of symptoms as adults even though the available data suggests otherwise, ignored smoking status that would attenuate responses in outdoor workers, and used human time/activity and exertion data from California as well as other locations. The USEPA analysis also used an algorithm to assign ventilation rates based on individuals who exercised regularly and were motivated to reach a high ventilation rate. As a result, the Staff Paper acknowledges[48] that the analysis allows more high ventilation rates than would actually occur in the populations of interest - outdoor workers, outdoor children, etc.

EPA staff used the analysis to evaluate estimated exposures of concern for a range of possible 8-hour standards between 0.07 and 0.09 ppm with from 1 to 5 allowed exceedances per year at each concentration. Based on the extensive discussion of which responses should be considered adverse and the detailed exposure analysis conducted by EPA that estimates the number of persons and occurrences of exposures that would be

[47] See USEPA Staff Paper at pages 59-72.
[48] See USEPA Staff Paper at page 102.

adverse, the CASAC conclusion was that there was no significant difference in public health risk among the alternative standards evaluated. [49]
When queried as to their preference or recommendation for the standard, no-one on the Clean Air Scientific Advisory Committee (CASAC) favored a 0.07 ppm 8-hour standard. They all preferred a multiple exceedance standard. Three CASAC members indicated a preference for a 0.08 ppm standard, three preferred 0.09 ppm, one indicated 0.08 or 0.09, one indicated 0.09 or 0.10, and two said it was strictly a policy decision.

When the USEPA Administrator promulgated the current 8-hour federal standard, she specifically considered a 0.07 ppm standard but chose a 0.08 ppm standard. She gave three reasons for the choice.[50] First, no-one on CASAC had recommended a 0.07 ppm standard. Second, the effects at issue are mild, transient, and reversible. Third, that 0.07 ppm was close to background levels that infrequently occur in some areas due to non-anthropogenic sources of ozone precursors and would inappropriately focus control on those non-anthropogenic sources.

The USEPA and CASAC specifically addressed the question of whether there should be one or two standards and clearly indicated that one standard was sufficient.

This comparison between the OEHHA and USEPA staff views on the public health significance of ozone effects demonstrates that additional analyses would help inform ARB's standard review. Additionally, the staff recommendation would have ARB establish a standard that is unattainable in California because of natural ozone and ozone from non-California sources. Therefore, a re-evaluation of the recommendation is warranted. First, the sections of the report reviewing the science should be revised in accordance with these and other comments. Second, a careful evaluation of the clinical significance of the mild, transient responses in chamber studies should be carried out. A range of experts outside ARB/OEHHA should be included in the evaluation. Third, an exposure/risk assessment that takes into account activity patterns and exercise levels should be carried out. Fourth, the risk from alternative standards should be evaluated by staff and the Air Quality Advisory Committee before a recommendation is prepared for ARB consideration.

Throughout this process, we recommend ARB Staff collaborate with their counterparts at the U.S. EPA in order to establish a common understanding of the science, to provide for a comprehensive explanation of any differences in interpretation of the science, and to reconcile legitimate differences and questions through further research if necessary. We consider it likely that through exploring such differences in interpretation of the science, will assist ARB in setting a standard based on sound science and will serve to abate some of the concerns of our industry and other interested stakeholders.

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[49] See CASAC Closure on the primary standard portion of the staff paper for ozone, EPA-SAB-CASAC-LTR-96-002, 1996.
[50] 62 Fed. Reg, 38868, July 18, 1997

A Recommendation for a Simple and Statistically Valid Procedure for Attainment Designation of Air Quality Standards

Submitted by the Alliance of Automotive Manufacturers
October 15, 2003

Executive Summary

The present California ambient air quality standards for ozone and PM are extremely stringent. They either overlap or are close to overlapping the ranges of variation of the respective concentrations observed in remote areas. Because the maximum values are used in the short-term standards, a procedure leading to the calculation of the Expected Peak Day Concentration (EPDC) has been devised to mitigate the potential impact of unusual events on the attainment designation of an area. However, the EPDC procedure is very complex, does not provide information on the degree of year-to-year variability of the concentration metrics used in the standards, and is not applicable to the annual standards. It is much simpler and more transparent to use straight three-year averaging to determine the designation value, and better yet, to also use the corresponding standard deviation coupled with the well-known t test to determine the attainment status of an area. The t test essentially raises a warning flag when the standard error is large, meaning that the three-year mean is not sufficiently precisely defined due to the large year-to-year fluctuation of the data. The lack of precision of the designation value that is near the level of the standard can allow one to meaningfully define the nonattainment-transitional and the attainment-transitional status for an area.

We also urge the California Air Resources Board to adopt the Federal forms of the standards for the different pollutants. These forms avoid the most extreme values in the data and reduce the need for procedures like the EPDC. They also incorporate the three-year means for increased robustness of the concentration metrics. In addition, our proposed procedure, especially with the t test, can be seamlessly applied to these standards for a meaningful determination of the attainment status of an area.

Text

The present California ambient air quality standards for ozone, carbon monoxide, sulfur dioxide, nitrogen dioxide, and suspended particulate matter all require that the designated values of the standards not be exceeded by corresponding observed concentrations. In the case of ozone and particulate matter (PM), the designated values of the standards (0.09 ppm for hourly ozone, 20 $\mu g/m^3$ for annual PM_{10}, 12 $\mu g/m^3$ for annual $PM_{2.5}$) are so low that they either overlap or are close to overlapping the range of variability of the already low background concentrations observed in remote areas of California.

The “never to be exceeded” requirement of the California air quality standards make the standards impractical. First of all, this requirement ignores the fact that ambient concentrations fluctuate due to meteorology, from day to day and from year to year; it is unreasonable to put an absolute upper bound on the concentrations, demanding a zero chance of occurrence for concentrations beyond a specific value. Secondly, the bound (the level of the standard) is so low that it is not far from the concentrations observed in the remote areas, and because each site must allow for some room to accommodate the year-to-year ambient concentration fluctuation, this means that the average maximum concentration must be significantly below the level of the standard for the site to stay in attainment indefinitely. This requirement further pushes the range of the concentration distribution toward that of the background concentrations. In other words, the “never to be exceeded” requirement makes the standard more stringent than it appears.

Because of the excessive stringency of the standard, coupled with the use of the maximum observed values in the standard, it becomes necessary for the California Air Resources Board to design a procedure to exclude “extreme” or “unusual” events from consideration for attainment designation of an area. For the short-term standards that deal with the daily concentration values, the Air Resources Board devised a procedure to calculate a metric called the Expected Peak Day Concentration (EPDC), which serves as a cut point to separate out ambient concentrations that may be considered a result of extreme concentration events. The highest observed concentration that is equal to or less than the EPDC in the three-year period used to calculate the EPDC is then considered as the designation value for comparison with the level of the air quality standard for attainment designation. Thus, even though the standard requires attainment every year, the use of three years of data in the EPDC procedure effectively allows the exclusion of some extreme concentrations within a three-year period. The EPDC has the following statistical problems. First, it is based on an assumed distribution (exponential), which is not necessarily the true distribution for the data. Second, it determines the exact location of the value corresponding to the probability of occurrence of one in 365. The procedure thus presumes that the data contain an infinite number of observations, which is clearly not the case in reality. And since extreme values are sensitive to the number of observations, with the expected extreme value increases with the number of observations in a right-uncensored distribution, the procedure has a tendency to yield a high value for the EPDC.

The EPDC is a result of weighted-averaging a very large number of metrics with the same probability of occurrence, but determined with different groupings of the upper-tail data from three separate but consecutive years of observation. The weights in the averaging are determined from the chi-square values of the goodness-of-fit tests for the different constructed exponential distributions. There is also a mysterious calibration factor, to be applied as an exponent to the final weighted average of the separate tail results, the calibration factor being 0.983 for ozone. This calibration exponent may mitigate the tendency of overestimating the EPDC value due to the presumption of an infinite number of observations in the data. The elaborate procedure is to smooth out the tail distributions of the data as much as possible so that any significant deviation from this distribution in the observed data can be considered “unusual” or “extreme” and can thus be ignored.

We find the procedure to be unnecessarily complicated with arbitrary assumptions imposed on the nature of the data. Furthermore, the EPDC procedure is designed to handle only the unusual extreme events within a year; it is incapable of handling the presence of an unusual year due to the year-to-year variation of the concentrations. We propose that a much simpler and much more transparent procedure be used to directly determine the designation value, while taking into consideration the degree of fluctuation in the metric used in the standard. This procedure is the well-known simple averaging over the data in a three-year period, with the confidence interval being determined by the standard deviation of the data. If the standard deviation is large (say, >0.015 ppm), that is an indication that unusual behavior may be present in the data. The larger the standard deviation, the more certain one can be of the presence of unusual events. Consideration of this unusual behavior will become important as a county or an area is approaching the attainment of the standard. In this condition, the well-known t test can be used to prescribe the attainment, nonattainment, nonattainment-transitional, and even the attainment-transitional status, which is not presently defined. The “data” here refers to the annual maxima, which in our opinion is not a practical statistical choice. It would have been more reasonable to use a less extreme metric similar to that used by the EPA, namely, the three-year mean of the annual fourth highest for ozone, or the three-year mean of the 98^{th} percentile for PM. Using a less-extreme form of the standard also reduces the concern for extreme events within a year, and the year-to-year fluctuation of the concentrations will be competently indicated by the size of the standard deviation in our proposed procedure.

The present EPDC cannot be used for annual means, and the procedure for assessing the presence of an unusual year in the data have been effectively ignored by the Air Resources Board. Our proposed procedure, on the other hand, can be applied to annual means as well with equal validity as in the case of the short-term standards.

We can provide more details to the simple proposed procedure if necessary. We also believe a comparison of the proposed procedure with that based on the EPDC for the attainment designation of the short-term standards would be very useful, especially when the t test is also used for the purpose of attainment designation. Last but not least, we urge the California Air Resources Board to consider seriously adopting similar, and preferably, identical, forms of the standards as that of the Federal standards.

The following table describes the advantages of our proposed procedure relative to the EPDC procedure for the determination of the designation value (DV).

Proposed Procedure	**EPDC Procedure**
Calculates the three-year mean and standard deviation of the standard metric	Uses a large number of exponential distributions to fit different sets of upper-tail data from each of three years, weight-averages the results from the three years of data for the quantile corresponding to the probability of occurrence of 1 in 365. Uses a calibration factor (exponent).
Consistent with extreme-value statistics	Exaggerating the extreme values by assuming an infinite number of observations; but used only as a cut point; a calibration factor (exponent) of <1 mitigates the exaggeration. Exponential distribution is an unproven assumption for the data.
Very simple and transparent	Very complex
Explicitly equivalent to using a three-year average as the form of the standard	Effectively similar to using a three-year weighted average as the form of the standard
Uses standard deviation to characterize concentration fluctuations; large fluctuations are indicated by large standard deviation	Presumably robust for concentration fluctuations within the same year, but cannot handle year-to-year fluctuations.
Can be used to determine the DV directly	Used as a cut point to remove unusual events
Can be combined with the simple t test to prescribe the attainment, nonattainment, nonattainment-transitional, and also attainment-transitional (proposed) status of an area.	Provides no information on the variability of the concentration data and cannot be meaningfully coupled with a statistical test for attainment status determination.
Can handle annual-mean standards as well	Cannot handle annual-mean standards