State of California

Governor Arnold Schwarzenegger

Air Resources Board

**Office of Environmental
Health Hazard Assessment**
Joan E. Denton, Ph.D.
Director

March 30, 2005

Dr. Mary Ross
United States Environmental Protection Agency
Office of Air Quality Planning and Standards, C539-01
Research Triangle Park, North Carolina 27711

Dear Dr. Ross:

We are writing in response to the United States Environmental Protection Agency's (USEPA) request for comments on the second draft of the "Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper." We are pleased to continue our participation in the review process, and appreciate the opportunity to comment on the recommended National Ambient Air Quality Standards (NAAQS) for particulate matter (PM).

Staff from the California Air Resources Board (ARB) and the Office of Environmental Health Hazard Assessment (OEHHA) have reviewed the second draft of the Staff Paper. We believe the recommended standards for PM2.5 and PM10-2.5 are improved and provide more health-protective options. There is a wealth of recent literature suggesting a strong correlation between adverse health effects and exposure to PM at concentrations which meet or exceed the current NAAQS. Because of the serious nature of PM exposure in California and the voluminous scientific literature demonstrating a clear association between PM exposure and adverse health effects, the ARB adopted stringent PM standards in 2002. Therefore, we urge USEPA to adopt standards at the low end of the recommended ranges. Considering the considerable public health impacts that could be avoided, including premature death, cardiovascular disease, and childhood asthma, setting the standards at the low end of the range is certainly warranted.

Attached are specific comments from ARB and OEHHA on the rationale for the lower standards. We hope you find our comments useful. If you need additional information or clarification, please contact Bart Croes, Chief of the ARB Research Division, at (916) 323-4519 or bcroes@arb.ca.gov, or Bart Ostro, Chief of the OEHHA Air Pollution Epidemiology Unit, at (510) 622-3157 or bostro@oehha.ca.gov.

Sincerely,

/s/

Catherine Witherspoon
Executive Officer
Air Resources Board

/s/

Joan E. Denton, Ph.D., Director
Office of Environmental Health
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Attachment

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California Air Resources Board and
Office of Environmental Health Hazard Assessment

Comments on the

Review of the National Ambient Air Quality Standards for Particulate Matter:
Policy Assessments of Scientific and Technical Information
OAQPS Staff Paper Second Draft

March 30, 2005

Introduction

There is a growing body of epidemiological evidence suggesting a causal association between ambient particulate matter (PM) and a range of adverse health effects. Strong associations are reported for PM exposure and diminished lung function, hospital and emergency room admissions for respiratory or cardiovascular disease, and premature mortality. Recent data also suggest a correlation between PM exposure and cardiovascular risk factors, such as heart rate variability and C-reactive protein. Preliminary reports suggest that there may also be an association between exposure to particulate pollution and certain pre- and post-natal developmental effects such as low birth weight and infant mortality. We would like to stress the importance of considering a number of subgroups identified as being more susceptible to PM-associated health effects as a result of their disease status, including individuals with cardiovascular disease or diabetes and children with asthma. Likewise, other subgroups have increased vulnerability to the effects of PM because of socio-economic status and/or residential location. There is increasing evidence that adverse health effects may be associated with PM concentrations as low or lower than the recommended standards contained in the Staff Paper. In consideration of the far-reaching consequences of this standard-setting process, we would like to stress the importance of establishing a PM standard that is protective of public health with an adequate margin of safety.

In general, the Air Resources Board (ARB) and the Office of Environmental Health Hazard Assessment (OEHHA) support the assessment of the literature and the proposed ranges for the PM2.5 standards. Specifically, we recommend a **PM2.5 annual average of 12 $\mu g/m^3$** and a **24-hour standard of between 25 and 30 $\mu g/m^3$ using the 99th percentile**. Given the wealth of data indicating the prevalence of health effects at lower PM2.5 concentrations, we believe adequate protection of public health necessitates a standard at or near the low end of the proposed range. Based on the risk assessment in the Staff Paper, lowering the 24-hour average to 25 or 35 $\mu g/m^3$, even with an annual average of 12 $\mu g/m^3$, would result in significant reductions in severe adverse health outcomes.

We acknowledge that there is greater uncertainty in the range of effects associated with coarse particles. However, some data suggest an association between coarse particle exposure and increased hospitalization and mortality. We believe your proposed 24-hour coarse particle standard of 75 to 85 $\mu g/m^3$ [99th percentile] is too high. Also, we recommend that you consider adding an annual average standard. Based on our own concerns of coarse particle effects, we retained a PM10 annual average in California.

In our recent review using a similar set of studies as USEPA, we determined that our PM10 annual average was not protective enough of public health, and consequently lowered it to 20 μg/m^3.

Scientific evidence supports the adoption of standards that provide increased protection not afforded by the current standards. More protective standards would reflect the generally strong body of literature showing associations between mortality and morbidity and exposure to lower levels of PM. Additional rationales for our recommendations are found below.

General Comments on Recommended Standards

PM2.5 Standards

We concur with the Criteria Document (CD) and Staff Paper assessment that there is a growing body of evidence associating PM2.5 with mortality and morbidity. The data consistently suggest that the PM2.5 fraction is highly correlated with particulate-related health effects. In addition, recent studies using a variety of methodologies have made major progress in dealing with existing issues regarding the associations between particulate matter and adverse health. For example, Schwartz et al. (2004) and Bateson and Schwartz (2001) used case-crossover methods to examine potential confounding by other pollutants and by weather. The case-crossover method is very effective at eliminating the concern for confounders by examining varying PM concentrations, while keeping the potential confounders, such as temperature or co-pollutants, constant. Results indicated that the association between particulate matter and mortality was not confounded by either gaseous co-pollutants or by temperature and seasonality (Bateson and Schwartz. 2001; Schwartz, 2004).

New studies published since the close of the Criteria Document have reported on associations between long-term particulate exposure and a range of adverse effects. For example, Kunzli et al. (2005) found an association between long-term PM2.5 exposure (mean 20 μg/m^3) and increased carotid intima-media thickness, a measure of subclinical atherosclerosis. Pope et al. (2005) reported significant associations between long-term exposure to PM2.5 (mean 17 μg/m^3) and mortality from heart failure, cardiac arrest, dysrhythmias, and ischemic heart disease in the American Cancer Society (ACS) Cohort. Stronger associations between PM exposure and cardiovascular effects were found using only the most recent two years of PM2.5 data, corresponding to a lower mean concentration (14 μg/m^3) (Pope et al., 2005).

These findings are supported by new studies of long-term PM2.5 exposure presented as abstracts at the last annual meeting of the International Society of Environmental Epidemiology. For example, using the Woman's Health Initiative Observational Study Cohort of 64,000 postmenopausal women with no history of cardiovascular disease, Miller et al. (2004) reported associations between long-term exposure to PM2.5 (mean 13.5 μg/m^3) and both fatal and non-fatal cardiovascular events. The authors calculated a hazard ratio of 14% associated with every 10 μg/m^3 change in PM2.5 (Miller et al., 2004). Analysis of the Seventh Day Adventist Cohort yielded similar associations between long-term PM2.5 exposure and mortality (all-cause and cardiopulmonary) in females (Knutsen et al., 2004). Jerrett et al. (2004) improved the exposure assessment within the ACS Cohort by interpolating among the 23 PM2.5 monitors in the Los Angeles air basin. Using this improved exposure analysis, it was found that a relative risk (RR) of 1.11 was associated with every 10 $\mu g/m^3$ PM2.5 (Jerrett et al., 2004), versus a RR of 1.06 from the previous analyses (Pope et al., 1996; 2002). Finally, Schwartz and Laden (2004) reported on a reanalysis of data from the Harvard Six-City Study. Using a Bayesian model averaging approach to better deal with uncertainty regarding the correct model specification, they reported a RR of 1.12 for every 10 $\mu g/m^3$ PM2.5 (Schwartz and Laden, 2004). While there are examples of studies that have not found an association between long-term exposures and cardiovascular effects, a majority of the literature supports such associations.

New PM2.5 studies published since the close of the Criteria Document also show an effect from short-term exposures. Pope et al. (2004) reported an association between PM2.5 (mean 24 $\mu g/m^3$) and changes in heart rate variability and C-reactive protein, both being associated with cardiovascular disease. Zanobetti et al. (2004) reported associations between PM2.5 and both diastolic and mean arterial blood pressure among subjects with pre-existing cardiovascular disease. The strongest association was found with a PM2.5 exposure (mean 14 $\mu g/m^3$) in the two days immediately preceding the blood pressure measurements. Taken together, these short-term and long-term exposure studies suggest that PM2.5 may initiate or exacerbate cardiovascular disease by mechanisms such as accelerated atherosclerosis, changes in cardiac autonomic function, and inflammation.

The consideration of an annual PM2.5 standard correctly places significant weight on the studies that report robust associations between long-term PM2.5 exposure and mortality (Dockery et al., 1993; Pope et al., 1995; Krewski et al., 2000, Pope et al., 2002). The mean PM2.5 concentrations associated with mortality were 18 $\mu g/m^3$ in the Six-Cities Study (range 11.0-29.6 $\mu g/m^3$); 21 $\mu g/m^3$ in the original ACS study (range 9-34 $\mu g/m^3$); approximately 14 $\mu g/m^3$ in the most recent analysis of the ACS study and 17 $\mu g/m^3$ when using the average of data from 1979-1983 and 1999-2000 (Dockery et al., 1993; Pope et al., 1995; Pope et al., 2002). It should be noted that the strongest associations (based on p-values) were reported with PM2.5 data from 1999-2000.

Until recently, there was no clear mechanistic explanation for the observed epidemiological findings of mortality and morbidity following acute or subacute exposure to ambient particles. Findings from current toxicological and epidemiological studies point to several biologically plausible mechanisms that may underlie the effects observed in time-series investigations. The basic pathophysiological models of PM-related health impacts begin with deposition of PM in the airways and the alveoli, which may lead to inflammation and possibly result in permanent or reversible damage to the lung. Chronic lung diseases, including asthma, emphysema, and chronic bronchitis, all involve ongoing inflammation in the lung. Additional inflammatory stimuli in the lungs could exacerbate these conditions, resulting in bronchoconstriction, respiratory symptoms, and possibly reduced blood oxygenation. Chronic inflammation may also facilitate PM-induced release of pro-inflammatory mediators, resulting in additional pulmonary inflammation and systemic (e.g., cardiac) effects. Acute responses to PM may also involve effects on the autonomic nervous system and changes to the biochemical composition of the blood. While the mechanistic evidence is still developing, it represents a dramatic advance from a few years ago, and serves to provide a framework of biological plausibility for the time-series and cohort studies.

Appropriately, the Staff Paper noted that thresholds were not apparent in the reviewed studies, and that the observed associations were linear or near linear. Graphical analyses suggest a continuum of effects down to lower levels of PM2.5 exposure (Dockery et al., 1993; Krewski et al., 2000). In the ACS study, uncertainty in the risk estimate becomes apparent at around 13 $\mu g/m^3$. The confidence intervals widen substantially as the concentrations extend further away from the study means (Krewski et al., 2000). In Dockery et al. (1993), the relative risks are similar for the cities at the lowest long-term PM2.5 concentrations of 11 and 12.5 $\mu g/m^3$. Larger increases in risk were not observed until the long-term PM2.5 mean was 14.9 $\mu g/m^3$ (Dockery et al., 1993). Thus, it appears that 12.5 to 13 $\mu g/m^3$ is a clear effect level. Defining 12.5 to 13 $\mu g/m^3$ as the level of concern is supported by the more recent long-term exposure studies cited above. However, a margin of safety should be factored into the formulation of the standard. It should also be recognized that adverse health impacts might occur at exposures below the mean concentrations in the published reports. The Staff Paper cited studies with associations between daily counts of cardiovascular mortality and long-term 24-hour mean PM2.5 levels in the range of 13 to 14 $\mu g/m^3$. In a recent review of the state particulate standard, California determined that an annual standard of 12 $\mu g/m^3$ should be the goal for long-term PM2.5 concentrations. This standard was promulgated following a public comment period and a peer review by an independent board of scientists (the Air Quality Advisory Committee or AQAC) appointed by the University of California, Office of the President. A 12 $\mu g/m^3$ standard would be consistent with the robust association with mortality effects. **Therefore, we urge consideration of a PM2.5 annual average of 12 $\mu g/m^3$.**

The risks per $\mu g/m^3$ of PM10 or PM2.5 are relatively small. However, when both total exposure and the size of the population exposed are considered, the overall health impact is substantial. In California, we utilized a methodology similar to that used by USEPA for estimating the benefits of Section 812 of the Clean Air Act and for several regulatory impact analyses (ARB, 2002). We estimated that, relative to an annual average of 12 $\mu g/m^3$, current PM2.5 exposures were associated with 6,500 premature deaths per year in California (95% C.I. = 3,200 to 9,800). Nationwide, Shprentz (1996) estimated that approximately 41,000 premature deaths per year could be avoided by attainment of a 12 $\mu g/m^3$ annual average.

Finally, we concur with the Staff Paper analysis of spatial averaging in Section 5.3.6.1. Epidemiological evidence supports the possibility that certain subgroups are differentially impacted by long-term exposure to air pollution. Therefore, consideration of single sites rather than averages among many sites is appropriate in order to determine whether the public is being protected with an adequate margin of safety. **Thus, we support the elimination of the provision that allows for spatial averaging for the form of the annual average standard**.

PM2.5 24-hour Average

There are hundreds of studies reporting associations between short-term (i.e., daily) exposures to PM10 and both mortality and morbidity. There are fewer short-term studies for PM2.5. What is clear is that the current federal 24-hour average standard of 65 $\mu g/m^3$ is not health-protective. Existing epidemiological studies report associations between mortality and morbidity with 24-hour average concentrations below 65 $\mu g/m^3$. Therefore, we support the proposal of a standard well below the current 24-hour standard. As cited in the Criteria Document, several studies reported adverse health outcomes associated with mean PM2.5 24-hour concentrations between 12 to 15 $\mu g/m^3$ (with the 99th percentile in the 35 to 45 $\mu g/m^3$ range.) (See also Table A-1, Memorandum on updated statistical information on air quality data from epidemiological studies, January 28, 2005.) Protection of public health necessitates a standard at the low end of the proposed range and one that provides an adequate margin of safety below concentrations that are associated with adverse effects. **Therefore, we support, as does the existing science, a 24-hour standard in the lower end of the proposed range, and no greater than 25 - 30 $\mu g/m^3$ for the 99th percentile.**

The Staff Paper risk assessment suggests that moving the 99th percentile 24-hour average from 40 $\mu g/m^3$ to 25 or 30 $\mu g/m^3$ would result in decreased mortality. The risk assessment suggests that a decrease in the 24-hour average would result in a 34% reduction in mortality in Los Angeles and a 45% reduction in mortality in Pittsburgh (Table 5-2). By using the risk assessment in the ARB Staff Report (2002, Table 9.4) and the Krewski et al. (2000) coefficient, we found that moving from current (1998-2000) concentrations to a 12 $\mu g/m^3$ annual average would prevent approximately 6,500 premature deaths in the state of California and approximately 2,800 premature deaths in Los Angeles County, alone. In moving from the 99th percentile of 40 $\mu g/m^3$ to 30 $\mu g/m^3$, the resultant 34% reduction, if applied to the whole county, would represent a decrease of an additional 950 premature deaths in Los Angeles County. When using the USEPA risk estimates for the city of Los Angeles, moving the 99th percentile from 40 $\mu g/m^3$ to 30 $\mu g/m^3$ would prevent 500 additional premature deaths. Based on the USEPA risk assessment, such risk reductions would likely occur in other cities, as well.

PM10-2.5 (Coarse Particle) Standard

In our recent review of the California ambient air quality standards for PM, we retained the annual average standard for PM10 but lowered it from 30 to 20 $\mu g/m^3$. The PM10 metric encompasses both fine and coarse particles. Our concern for controlling the coarse fraction was based largely on a review of studies similar to those reviewed in the Criteria Document that demonstrated increased risks of mortality and morbidity. Our own evaluation of the data and the robustness of the PM10 literature led us to retain the PM10 standard rather than develop a separate coarse particle standard.

As reviewed in the Criteria Document, and summarized in the Staff Paper, there are several studies attributing adverse health effects to coarse particle exposure. For example, Burnett et al. (1997) reported an association between coarse particles (mean = 11.5 $\mu g/m^3$, 99th percentile = 36 $\mu g/m^3$) and both cardiovascular and respiratory hospitalizations during the summer in Toronto, Canada. Castillejos et al. (2000) found an association between daily coarse particle exposures (mean = 17 μg/m^3, maximum = 55 μg/m^3) and mortality in southwestern Mexico City. The coarse fraction was not correlated with the fine fraction in this study. Associations have been reported between coarse particles and mortality in Steubenville (mean = 16 μg/m^3, 99th percentile = 61 μg/m^3; Schwartz et al., 2003) and hospitalization for asthma in Seattle (mean = 16 μg/m^3, 99th percentile = 39 μg/m^3; Sheppard, 2003). Higher concentrations (mean ~30 μg/m^3) were also associated with mortality (Ostro et al., 2003; Mar et al., 2003).

Evidence from longer-term exposure fails to show an association between coarse particles and premature mortality. It is unclear whether this is due to larger measurement error or simply an absence of an effect. Measurement error is likely to have a greater influence on the results of longer-term studies since coarse particles are generally not spatially heterogeneous. This may be a source of significant non-random error in particle measurement at a given fixed-site monitor. Such error may be less of a problem for time-series studies, where measurement error may be more consistent over the sampling period.

Based on the review of studies in the Staff Paper it is evident that a potential effect level of concern for coarse particles may be between 11.5 μg/m^3 and 30 μg/m^3 — the mean concentrations associated with particularly adverse health outcomes in several studies. The Staff Paper recommendation of 75 to 85 μg/m^3 (99th percentile) for the 24-hour standard may not be protective enough considering the evidence from the PM10 studies. We are concerned about the potential withdrawal of the annual coarse particle standard. Based on our own concerns of coarse particle effects, we retained a PM10 annual average in California, however recently lowered it to 20 μg/m^3 to maintain an adequate margin of safety.

Secondary PM Standard

In general, we find the overall discussion of secondary welfare effects of PM to be scientifically consistent. We have no substantive disagreement with the secondary standards. We have, however, made some additional comments about particle characterization in “Specific Comments,” below.

Specific Comments on the Document

Chapter 2: Characterization of Ambient PM

Section 2.2.2 - Source and Formation Processes. A balanced discussion of the sources of PM would be helpful. For example, although high PM10 concentrations are often associated with meteorological conditions conducive to dust suspension, anthropogenic sources (e.g., agricultural activities, construction and demolition, vehicle travel on paved and unpaved roads) are a significant source of PM10 in California.

Section 2.2.3 - Chemical Composition. This section needs more consideration of nitrate aerosol formation. Specifically, the heterogeneous chemical reaction between sea-salt particles and gas-phase nitric acid (leading to thermally stable sodium nitrate production in the particle phase accompanied by liberation of gaseous hydrochloric acid from the particles) is an important pathway in nitrate aerosol formation, particularly at coastal sites. This reaction may be the principal source of coarse (2.5 to 10 μm) nitrate, and additional discussion of this heterogeneous chemical reaction is needed.

Section 2.2.4 - Fate and Transport. This section has important omissions of national and worldwide efforts in the area of ultrafines particles. For example, recent measurements taken in southern California show a wide range in particle counts in different environments. The highest counts are found on or near busy roadways. Motor vehicles are a major source of ultrafine particles in the urban environment. Several studies show substantially high counts on and near freeways or near roadways, falling to much lower levels 100-300 m downwind. The two major component of ultrafines in Central and Southern California are organic carbon and elemental carbon, generally arising from primary emissions from local traffic and secondary reaction of gaseous precursors. A short discussion of these issues would be helpful.

Section 2.2.5 - Optical Properties of Particles. Again, it is important to include information about sources of particulate matter across the entire US. As such, this section should include a statement about black carbon (BC), desert dust, and other organic carbon species. Although off-road and on-road diesel engines are the major sources of BC, gasoline vehicles represent a smaller but non-negligible source of BC emissions. Due to the importance of these sources especially in terms of total number, on-road and off-road mobile sources likely contribute to significant BC emissions.

Section 2.2.6 - Radiative Properties of Particles. This section should include more detailed explanation about the optical properties of particles. Additional details about solar radiation scattering by sub-micron aerosol particles (< 1 μm) would be appreciated. Of all particulate species, BC exerts the most complex effect on climate. BC scatters a portion of the direct solar beam back to space, which leads to a reduction in solar radiation reaching the surface of the Earth. This reduction is manifest as increased solar radiation reflected back to space at the top of the atmosphere, that is, a negative radiative forcing (cooling). A portion of the incoming solar radiation is absorbed by BC-containing particles in the air. This absorption leads to a further reduction in solar radiation reaching the surface. Solar radiation that would otherwise reach the surface is prevented from doing so, resulting in further cooling. However, the absorption of radiation by BC-containing particles leads to heating in the atmosphere itself. Thus, absorption by BC leads to a negative radiative forcing at the Earth’s surface and a positive radiative forcing in the atmosphere.

Section 2.3.1 - Particle Mass Measurement Methods. There should be a brief discussion of both the difficulties associated with measuring PM mass in ambient air and the direct and indirect measurement techniques employed to determine PM mass. A description of the method limitations would be helpful, such as the inherent inaccuracy of indirect methods because of the lack of consistent physical connection between particle mass and other particle properties (i.e., particle size distribution or optical properties). To measure mass directly, particles need to be collected (typically on filters) and weighed. PM is composed of chemical species exhibiting widely varying vapor pressures. As a consequence, weighing a filter after particle collection can result in a questionable measure of PM mass. This problem is exacerbated with fine particle mass measurements because the greater surface area to mass ratio, as well as the composition of fine PM, results in significantly greater volatile fraction of mass compared to coarse PM.

Section 2.3.2 - Particle Indirect Optical Methods. This section was too brief and needs to include a discussion on problems associated with the characterization of PM by indirect optical methods. The results of several studies suggest that sulfate and organic species are major contributors to light scattering, with the contribution of nitrate being more variable. This should be included in the Staff Report. Likewise, a discussion of the effect of humidity is needed. For example, humidity levels above 70% strongly influence particle light extinction. The effect of humidity on light scattering properties is also very dependent on chemical and microphysical variables, as components of fine particles (hygroscopic fraction of aerosol) will vary their ability to absorb water. Although data suggest there are common optical properties for the fine particle fraction, it would be inappropriate to claim that PM2.5 mass and light scattering coefficients are equivalent, either temporally or spatially. The high-time resolution light scattering data (i.e., hourly measurements) clearly indicate that aerosol variation is significant on both seasonal and monthly time scales. There is also a measurable diurnal variation of up to 50% of the daily average values where primary particle emissions are significant. The light scattering-humidity relationship depends on the particle composition, microstructure (i.e., internally or externally mixed aerosols), and the history of relative humidity values previously experienced by the particles. Hence the relationship between fine particle mass and light scattering can be obscured by many physical/chemical factors and sampling errors. All of these factors should be examined carefully before the use of any scattering data for estimating fine mass concentration.

Section 2.3.3 - Particle Number Concentrations Measurement Methods. This is a very incomplete section and it should be expanded. Aerosol sizing instruments may be divided into categories based on the measurement principle. Each instrument measures some property of the aerosol (i.e., electrical mobility, aerodynamic diameter, and optical behavior), and relates each property to size. It would be helpful to include a table listing the most commonly used instruments for measuring particle size distribution.

Section 2.3.4 - Chemical Composition Measurement Methods. This section should discuss limitations of existing methods for measuring chemical composition, particularly for organic carbon (OC) species. Organic particulate matter is an aggregate of hundreds of individual compounds spanning a wide range of chemical and thermodynamic properties. Some of the organic compounds are “semivolatile” such that both gaseous and condensed phases exist in equilibrium in the atmosphere. The presence of semivolatile or multiphase organic compounds complicates the sampling process. While many advances have been made in measuring and modeling the inorganic ionic species that are found in PM2.5, much less is known about the organic fraction.

Section 2.3.5 - Measurement Issue. This section should discuss nitrate artifacts in PM sampling methods. A large body of evidence has accumulated in recent years that a significant fraction of particle nitrate can be volatilized from Teflon filters during sampling. This may occur during sampling on other filter media where, under certain conditions, volatilization losses can be large. Because particulate nitrate is a major component of PM in western US, especially in California, the loss may significantly affect the gravimetric mass measurement. Recent data indicate that the ammonium nitrate volatilization effect on measured mass is site-dependent, and depends on the meteorological conditions and the fraction of PM mass that consists of ammonium nitrate particles. There is no straightforward method to correct for the mass loss without measuring it. The highest mass loss found at selected sites occurred during summer daytime in southern California, amounting to 30-50% of the gravimetric mass.

Section 2.4.4 - Ultrafine Particles - Concentrations. While these studies are often referenced as saying levels of ultrafine particle counts diminish to background levels within 200-300 m of freeways, this is likely to be a major oversimplification. Wind speed and meteorology can allow counts to persist far beyond this distance. Careful examination of the papers and the results of dispersion modeling suggest that the values remain in excess of “background” beyond 300 m. It is probably very misleading to use the term background because of the imprecise definition. It is clear that air upwind of the I-405 or I-110 freeways are not the pristine air many people think of as background.

Section 2.5.2 - Ultrafine Patterns – Temporal Patterns. This is a very incomplete section and it should be expanded. In it you state ultrafine particle number concentrations in Atlanta, GA were found to be higher in the winter than in the summer and that particle concentrations in the range of 0.01 to 0.1 µm were higher at night than during the daytime. Recent measurements taken of southern California show a wide range in particle counts in different environments. The highest counts are found on or near busy roadways. In the urban environment, motor vehicles are a major source of ultrafine particulates. Results of a study show that normalized particle number concentration tracked the traffic density very well indicating that traffic is the major contributor to fine and ultrafine particles. Wind speed and direction are also important in determining the characteristic of ultrafine particles near freeways. The stronger the wind, the lower the total particle number concentration. Total particle number concentration is directly related to traffic density and decreases significantly during a traffic slowdown. Exponential decay was found to be a good estimator for the decrease of total particle number concentration with distance along the wind direction. Measurements show that both atmospheric dilution and coagulation play important roles in the rapid decrease of particle number concentration and the change in particle size distribution with distance away from a freeway.

Chapter 3: Policy-Relevant Assessment of Health Effects Evidence

The chapter appropriately acknowledges that the recommended standards are based on epidemiological data. The relevant studies identified as key to the assessment of health effects are also appropriate. There is an adequate discussion of the assumptions and limitations of the studies, as well as an understanding that the conclusions drawn from such studies have an inherent degree of uncertainty. Since the proposed standards are based on epidemiological data, it is necessary to address both the adequacy and nature of the statistical model specifications and whether or not there is an effect threshold. The description of dosimetry and deposition provides a nice overview that accurately reflects the available data. The Staff Paper properly acknowledges that multiple biological mechanisms may mediate PM-related health effects. We also appreciate the consideration of both susceptible and vulnerable subpopulations.

Sections 3.2 and 3.3.2.2 - Mechanisms and Effects on the Respiratory System. There is some discussion of toxicological and human study findings. However, it is unclear what PM sizes or concentrations were associated with the observed effects. In addition, it would be helpful to put the toxicological and epidemiological findings in context of the likelihood of observing adverse effects at environmentally relevant exposures.

Chapter 4: Characterization of Health Risks

Overall, the uncertainties and assumptions used in the risk assessment are properly and clearly defined. The report appropriately emphasizes the relevance of long-term exposure in developing the recommendations. While it is inappropriate to include mechanistic type studies (i.e. heart rate variability) in the risk assessment, it is unclear why emergency room visits were not included.

Section 4.2.7 - Characterizing Uncertainty and Variability. It would be useful to indicate, either quantitatively or qualitatively, how the risk estimates vary with the model specifications in the underlying epidemiological studies. For example, how much do the estimates vary based on different controls for weather, long-term trends, seasonality, and other pollutants?

Section 4.3.3 - Key Observations. Greater explanation is needed for Figure 4-8b. Are the uncertainty estimates based solely on the confidence intervals for the estimated pollution coefficient of the original Ito (2003) study?

Section 4.5 - Risk Estimates Associated with Alternative Standards. Please clarify how risk estimates from areas with many monitors and complex PM levels might differ from those with a few or very uniform PM levels. In addition, it would be helpful to include a clear discussion of how selection of a single maximal site for a risk calculations may apply to an entire basin, such as Los Angeles. There is a brief summary that could be moved up from page 4-81.

Section 4.5.2 - Base Case for Alternative PM10-2.5 "Coarse" Standards. This section is difficult to read. The authors did not explain (on page 4-75, line 10-11) why the confidence intervals around the estimates widen as lower daily standards are considered. A more detailed explanation would help clarify issues, such as whether the limited sample size (i.e., less days) resulted in wider confidence intervals.

Chapter 5: Staff Conclusions and Recommendations on Primary PM NAAQS

It is evident that a combination of an annual and a 24-hour standard is needed to provide adequate public health protection. Elimination of the current provision allowing spatial averaging in the form of the annual PM2.5 standard is a positive step toward improving the health protectiveness of the annual standards. The approach used to select the annual standard based on the health data and the 24-hour standard based on air quality modeling is a relatively new approach requiring further justification.

The Clean Air Act specifies that ambient air quality standards should protect the public with an adequate margin of safety. None of the alternative recommendations will reduce estimated mortality to zero, which the report acknowledges. What is missing is a discussion of what constitutes an acceptable risk. The discussion of the differences between the 98th and 99th percentiles needs to be clarified and expanded, as does the discussion of the criteria for attainment designations. Although these topics are mentioned briefly, the report should more clearly explain why the 98th percentile allows seven (7) exceedences per year, while the 99th percentile allows three to four (3-4) exceedences, and how each relates to the attainment designation process.

We are concerned that the annual average may be withdrawn altogether, largely because consideration of an annual average may provide a margin of safety while researchers continue to elucidate the effects (morbidity and mortality) of thoracic coarse particles. Of the few short-term studies available, the data reviewed were used appropriately in developing the findings. However, given the discussion of the Toronto, Seattle, and Detroit data, the primary recommendation of 65-85 $\mu g/m^3$ is too high.

Section 5.3.4.2 - Risk-based Considerations. More discussion is needed on the “form” considerations. This will likely be quite controversial and pivotal in defining the stringency of proposed standards. It is also not transparent to most readers. The text that summarizes the issue does not appear until section 5.3.6.

Chapter 6: Policy-Relevant Assessment of PM-Related Welfare Effects

Section 6.5.1 - Climate Change and Potential Human Health and Environmental Impacts.

Ozone and airborne particulate matter are the two primary ingredients of photochemical smog. Temperature is one of the most important meteorological variables influencing air quality in urban atmospheres because it directly affects gas and heterogeneous chemical reaction rates and gas-to-particle partitioning. Previous studies have considered the effect that reduced emissions rates have on ozone and PM2.5 concentrations. Relatively little work has been done to consider the simultaneous effect of variable meteorological conditions on the size and composition distribution of airborne particulate matter. The impact of climate change on PM2.5 concentrations must be understood before the effectiveness of emissions control programs can be evaluated.

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