COMMENTS BY THE TEXAS COMMISSION ON ENVIRONMENTAL QUALITY REGARDING THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER; PROPOSED RULE

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I. Summary of Proposed Action

On June 29, 2012, the United States Environmental Protection Agency (EPA) published in the *Federal Register* proposed revisions to the primary and secondary National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) and corresponding revisions to the data handling conventions for PM and ambient air monitoring, reporting, and network design requirements.

With regard to primary standards for particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$), the EPA proposes to revise the annual $PM_{2.5}$ standard by lowering the level to within a range of 12.0 to 13.0 micrograms per cubic meter ($\mu g/m^3$) and to retain the current 24-hour $PM_{2.5}$ standard. With regard to the primary standard for particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}), the EPA proposes to retain the current 24-hour PM_{10} standard.

With regard to the secondary PM standards, the EPA proposes to revise the suite of secondary PM standards by adding a distinct standard for $PM_{2.5}$ to address PM-related visibility impairment and to retain the current secondary standards to address non-visibility welfare effects. The proposed distinct secondary standard would be defined in terms of a $PM_{2.5}$ visibility index, which would use speciated $PM_{2.5}$ mass concentrations and relative humidity data to calculate $PM_{2.5}$ light extinction, translated to the deciview scale, similar to the Regional Haze Program; a 24-hour averaging time; a 90th percentile form averaged over three years; and a level set at one of two options—either 30 or 28 deciviews.

II. Comments

A. Primary Standards for Fine Particles

The Texas Commission on Environmental Quality (TCEQ) does not support revision of the NAAQS as the proposal is based on flawed and incomplete analysis.

The proposed NAAQS (the proposal) states that the Administrator "concludes that the current primary $PM_{2.5}$ standards…are not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection" (EPA 2012, III.D.4). However, it appears that the EPA did not consider all of the available scientific evidence or adequately weigh the significant limitations and uncertainties in using observational epidemiological studies to set the proposed NAAQS. Furthermore, the conclusion to lower the NAAQS is based on two faulty assumptions: (1) that exposure to $PM_{2.5}$ at relevant environmental concentrations causes premature mortality; and (2) that the relationship between $PM_{2.5}$ exposure and the purported effect on mortality is linear with no threshold. Neither of these assumptions is borne out by the available epidemiologic or toxicological data. Based on these considerations, the TCEQ does not support revision of the NAAQS as the proposal is based on flawed and incomplete analysis.

Assumption that $PM_{2.5}$ causes mortality at environmentally relevant doses:

The current EPA analysis relies on selective inclusion of epidemiology studies that report small statistical associations between $PM_{2.5}$ exposure and health effects. However, these observational studies are exploratory in nature and designed to look for correlations (which are distinct from causation). These studies should not be used quantitatively, and they certainly are not rigorous enough to set environmental policy. Indeed, it has been reported that such studies are more prone to residual confounding than previously recognized (Greven et al. 2011).

The proposal presents only a portion of the available epidemiological evidence, fails to consider the unexplained heterogeneity in reported PM effects, and discounts negative data. Numerous studies have found no association between $PM_{2.5}$ and premature mortality, many at much higher doses than those measured in American Cancer Society (ACS) and Harvard Six Cities (HSC) cohort studies[1] upon which the proposal relies heavily. The EPA does not explain why contradictory data and inconsistent findings should be discounted in favor of studies that show small statistical associations.[2] The Policy Assessment appears to minimize the importance of studies that show no association between PM exposure and mortality: "we place greatest weight on those long- and short-term exposure studies that reported statistically significant associations with mortality and morbidity effects" (EPA 2011, 2.1.3). It is entirely inappropriate to misuse a weight of evidence approach to discount negative data. Taken together, a complete review of the available epidemiological data does not support the assumption that $PM_{2.5}$ causes premature mortality at current ambient concentrations.

The proposal specifically identifies three studies that are key in arriving at the determination to lower the NAAQS: the Women's Health Initiative (WHI) (Miller et al. 2007), the HSC (Laden et al. 2006), and the ACS (Krewski et al. 2009) cohorts. The proposal states that "the most important new evidence comes from the WHI study which provides evidence of nonfatal cardiovascular events including both coronary and cerebrovascular events" (EPA 2012, III.B.1). However, this study estimated cardiovascular deaths associated with exposure to $PM_{2.5}$ that are implausibly large (Jerrett and Burnett 2007). Furthermore, the effect of $PM_{2.5}$ on cardiovascular endpoints was nonsignificant for individuals with a college education, those younger than 69 years of age, non-smokers or those who lived with a smoker, individuals with lower Body Mass Index, or no history of hormone replacement therapy. Results such as these are difficult to interpret because no biological basis for such heterogeneous observations has been determined.

As the Quantitative Risk Assessment, Policy Assessment, Regulatory Impact Analysis (RIA), and resulting proposed NAAQS place a great deal of weight on the updated ACS study by Krewski et al. (2009), we provide additional detailed comments on this report. The authors assumed that the exposure-response relationship between exposure to $PM_{2.5}$ and different endpoints was log-linear at all exposure levels. That is, they did not consider models that include the possibility of a threshold (the exposure below which no deleterious effect is expected to occur). They also excluded from consideration nonlinear relationships in the exposure-response models. The Cox

[1] Krewski et al. 2000 (for models that include SO_2), McDonnell et al. 2002, Klemm and Mason 2003, Moolgavkar 2003, Koop and Tole 2004, Chen et al. 2005 (for males), Enstrom 2005, Lipfert et al. 2006, Franklin et al. 2007 (lag 0 data), Zeger et al. 2008 (for Western U.S.), Krewski et al. 2009 (for 1972-2000 data), Klemm et al. 2011, and Tony Cox 2011

[2] A member of the CASAC Particulate Matter Review Panel noted that the assessment did not address the heterogeneity of effects, especially the negative C-R coefficients for some areas, and recommended that the following language be included: "the range of potential unintended secondary adverse consequences have not been evaluated in this document. Thus the recommendations herein may, or may not, improve overall public health." (EPA-CASAC-10-015)

proportional hazards model and the extension to include random effects are appropriate modeling methods, but the models themselves may have not been fully specified due to lack of data, lack of understanding of biological mechanism and mode of action, and lack of flexibility in their model evaluation to include alternative exposure-response shapes. Sulfur dioxide (SO_2) exposure was not included when modeling mortality attributed to $PM_{2.5}$ exposure despite previous findings by the same group that this was an important confounding variable. In fact, when included in statistical models, this inclusion resulted in null associations between $PM_{2.5}$ and mortality (Krewski et al. 2000). Furthermore, the Health Effects Institute (HEI) review panel warns about the weak and inconsistent results in this study: "These divergent results argue for caution in extrapolating from such studies in any one metropolitan area to other areas." The weak and inconsistent exposure-response relationship between $PM_{2.5}$ and different endpoints found by Krewski et al. 2009 is an indication that some alternative modeling options and covariates may have been overlooked.

The ACS cohort also has specific weaknesses. As most of the air pollution data was collected decades ago, the applicability of this study to risks at current air quality is questionable. The socioeconomic data for this cohort was collected using a self-administered questionnaire that was collected in 1982 and never updated. Results have been found to be sensitive to confounding by SO_2 (Krewski et al. 2000)[3], but the version of this study utilized by the EPA does not address this issue (Laden et al. 2006). Furthermore, although the proposal refers to the updated findings from the ACS and HSC cohorts as "important new information," it is neither particularly compelling nor new evidence that associations noted in the past[4] are still observed.[5]

Perhaps the most persuasive evidence arguing against the assumption that ambient levels of $PM_{2.5}$ cause mortality is from the toxicological literature: neither animal nor human exposure studies have shown that $PM_{2.5}$ causes mortality when inhaled at environmentally relevant concentrations.[6] Furthermore, the proposed rule implausibly suggests that $PM_{2.5}$ causes mortality at lower levels than those required to elicit less serious effects in toxicological and clinical studies (Valberg 2004). In fact, the Policy Assessment states that "[t]oxicological studies provide supportive evidence that the cardiovascular morbidity effects observed in long-term exposure epidemiological studies are biologically plausible and coherent with studies of cardiovascular-related mortality as well as with studies of cardiovascular-related effects associated with short-term exposures to $PM_{2.5}$, as described below" (EPA 2011, 2.2.1). However, review of this evidence reveals that the majority of the cited data is not statistically significant. Therefore, it is unclear how the EPA arrived at the conclusion that this data supports plausibility of the selected epidemiology results. Indeed, referring to the results by Krewski et al. 2009 (a key study relied upon by the proposal), the HEI review committee concludes "The investigators referred to this association [between cardiovascular mortality and $PM_{2.5}$ exposure] as having 'high biologic plausibility,' but the Review Committee thought that the existing limited epidemiologic and mechanistic evidence, though suggestive, does not justify such a strong assertion."

The small effect sizes observed in the epidemiology studies used by the EPA may be indicative of confounding. Multiple agencies have cautioned against over-interpreting small relative risks

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[3] The Risk Assessment (EPA 2010) again confirmed the importance of this confounding effect of SO_2, reducing estimates for case study estimates by 74% (see Table F-43).
[4] Pope et al. 1995 and 2002 and Dockery et al. 1995
[5] Laden et al. 2006 and Krewski et al. 2009
[6] Green and Armstrong 2003, Schlesinger et al. 2007, Chen and Lippmann 2008, and Mauderly and Chow 2008

(less than 2.0).[7] In addition to such scientific guidance, legal precedence also indicates that relative risks below 2.0 should not be considered to support a hypothesized relationship. The Federal Judicial Center Reference Manual on Scientific Evidence Third Edition (2011)[8] provides the following guidance: "The higher the relative risk, the stronger the association and the lower the chance that the effect is spurious…because epidemiology is sufficiently imprecise to accurately measure small increases in risk, in general, studies that find a relative risk less than 2.0 should not be sufficient for causation. The concern is not with specific causation but with general causation and the likelihood that an association less than 2.0 is noise rather than reflecting a true causal relationship." In fact, a recent paper finds that cofounding could be playing a significant role in the statistical findings of positive $PM_{2.5}$ mortality associations. Greven et al. (2011) have developed a method for estimating risk coefficients based on changes in $PM_{2.5}$ within a given city as well as those shared across the nation. If $PM_{2.5}$ has a causal relationship (at ambient concentrations) with mortality risk, then these two risk coefficients should be similar. However, this approach demonstrates evidence of confounding in the national trends between $PM_{2.5}$ and premature mortality.[9] This observation is critical as it implies that the statistical studies of mortality risk attributed to $PM_{2.5}$ exposure may be detecting a spurious association. Therefore, mortality risk will not be reduced by changes in ambient $PM_{2.5}$, in agreement with the observed heterogeneity within and between epidemiology studies to date.

Assumption that there is no threshold below which $PM_{2.5}$ does not cause mortality:

The EPA also assumes that any exposure to $PM_{2.5}$, no matter how low, directly causes premature death. This assumption of no threshold extrapolates risk below both the NAAQS and the lowest measured levels of the available epidemiological studies, extending to background levels. This "no-threshold" approach is not appropriate, nor is it conclusively supported by the data.[10] In fact, ecological epidemiology studies have limited statistical power to identify concentration response relationships and thresholds of no effect. While this limitation does not prove that thresholds do not exist, a limited number of studies have been specifically designed to determine the existence of thresholds. In both short-term and long-term studies, thresholds for mortality attributable to PM have been observed, some at levels above the current NAAQS.[11]

The non-threshold assumption also presents difficulties when choosing an appropriate standard. This assumption will result in identification of risk at any level of $PM_{2.5}$ and will

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[7] http://benchmarks.cancer.gov/2002/07/epidemiology-in-a-nutshell/ "Relative risks or odds ratios less than 2.00 are viewed with caution." WHO/IARC: Breslow and Day (1980). Statistical methods in cancer research. Vol. 1. The analysis of case control studies. IARC Sci. Publ. No. 32, Lyon, p. 36. "Relative risks of less than 2.0 may readily reflect some unperceived bias or confounding factor, those over 5.0 are unlikely to do so." WHO: Craun and Calderon. How to interpret Epidemiological Associations. "An increased risk of less than 50% (RR=1.0-1.5)…is considered by many epidemiologists to be either a weak association or no association."

[8] Federal Judicial Center Reference Manual on Scientific Evidence-Reference Guide on Epidemiology (Green et al.)

[9] This group voiced similar concerns in a 2007 report by Janes et al. which would have been available for EPA review during the development of the Integrated Science Assessment, Risk Assessment, Policy Assessment, RIA and resulting proposed NAAQS.

[10] Krewski et al. 2000 (for models that include SO_2), McDonnell et al. 2002, Klemm and Mason 2003, Moolgavkar 2003, Koop and Tole 2004, Chen et al. 2005 (for males), Enstrom 2005, Lipfert et al. 2006, Franklin et al.2007 (for lag 0 data), Zeger et al. 2008 (for Western U.S.), Krewski et al. 2009 (for 1972-2000 data), Klemm et al. 2011, Tony Cox 2011

[11] Abrahamowicz et al. 2003, Daniels et al. 2000, Gamble and Nicolich 2006, Nicolich and Gamble 1999, Smith et al. 2000, and Stylianou and Nicolich 2009

predict risk associated with any hypothetical annual standard leaving the decision of what that standard ought to be arbitrary.

The EPA has failed to explain adequately the methods by which it has identified its recommended range of revised and alternative $PM_{2.5}$ NAAQS.

The proposed range appears to be based on the arbitrary designation of: "…levels that were **somewhat below** the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies" (EPA 2012, 3.A.3) (emphasis added). This is not a rigorous basis for selecting an alternative standard and certainly does not encompass the full range of reasonable alternatives. For instance, it is not clear why 14 μg/m^3 was rejected as the Risk Assessment found "notable reductions [in risk] ranging from 9% to 12% when modeling that alternative standard" (EPA 2011, 4.2.2). The Risk Assessment expressed highest confidence in the 14 to 13 μg/m^3 range and commented on specific uncertainties and limitations in the lower end of this range. However, the Policy Assessment states that an integrated weight of evidence approach adequately incorporating such uncertainties resulted in the proposed range of 13 to 11 μg/m^3. It is not clear then how the evidence supports the lower range as the Risk Assessment did not generate quantitative risk assessment for 11 μg/m^3, and the Policy Assessment notes substantially lower confidence in this range (EPA 2010, 2.3.4.4). The stated rationale is that long-term epidemiology studies show correlations between $PM_{2.5}$ levels below the current standard level of 15 μg/m^3 and premature mortality. However, along with the limitations described above, it is important to acknowledge that past exposure to historically higher concentrations are difficult to separate from the effects of lower current levels in these long-term studies such as the WHI (Miller *et al.* 2007), ACS (Laden *et al.* 2006), and the HSC (Krewski *et al.* 2009) studies.

Given that "[a] number of the other study areas did not exhibit notable risk reductions" (EPA 2010, 4.2.4) within the chosen range of 12 to 14 μg/m^3, it appears that the proposed level ranging from 12 to 13 μg/m^3 will be overly stringent in many areas of the country (see results in Risk Assessment for Dallas, Los Angeles, New York, Philadelphia, Phoenix, Pittsburgh, Salt Lake City, Tacoma, and Fresno - i.e., 9 of 15 case-study areas).

B. Secondary Standards

The distinct secondary standard as proposed by the EPA addressing PM-related visibility impairment is very poorly justified, not supported by quantitative data, and duplicative and any efforts to address any PM-related visibility concerns in urban areas should be done in other programs, such as the Regional Haze Program, the $PM_{2.5}$ permitting program, and other initiatives.

The EPA proposes to revise the current set of PM secondary standards to add a distinct secondary standard for $PM_{2.5}$ addressing PM-related visibility impairment in urban areas as distinguished from the Federal Clean Air Act (FCAA), §169B requirement to protect Class I areas. The EPA also proposed to retain the current $PM_{2.5}$ and PM_{10} secondary standards related to other welfare effects. The EPA asserts that proposing to add a new secondary standard for $PM_{2.5}$ addressing visibility impairment in urban areas is necessary to "reflect an evolution in…the nature of the effect on public welfare from visibility impairment." The TCEQ contends that setting a new PM-related secondary standard for visibility in urban areas at a national level is intensely problematic and that any attempt to address PM-related visibility issues in urban areas should be coordinated with the EPA's specific authority related to visibility in FCAA, §169A and §169B. The programs established in those sections of the FCAA provide flexibility both for the EPA and the states while also reducing the possibility of competing guidance and methodologies for implementation purposes.

In the proposal, the EPA stated it has considered the unique issues presented with promulgating a secondary standard addressing visibility issues in urban areas over the years, and it had concluded that the implementation of a standard at a national level could be complicated by purely regional issues, including background concentrations of air constituents and average relative humidity. In 1999, the EPA promulgated the Regional Haze Program, which requires states to improve visibility in affected areas through State Implementation Plan (SIP)-approved control strategies. EPA relies on the research conducted as a result of the promulgation of the Regional Haze Program to propose new PM-related secondary standards to control visibility impairment in urban areas. While the EPA proposes that setting a distinct secondary standard is necessary to reduce the adverse effects of air constituents on urban visibility, it does not detail in the proposal exactly how studies related to the impairment of visibility in Federal Class I areas (typically national parks, etc), replete with those unique regional traits (background concentration and relative humidity) that the EPA has acknowledged are problematic to establishing a national standard, *now* evidence the need to set a distinct secondary NAAQS to protect the public welfare in urban areas. Thus, any promulgation of any new visibility standards should be coordinated with rulemaking associated with FCAA, §169A and §169B because of established implementation guidelines and policies associated with those sections.

By relying on one set of established guidelines and policies rather than creating new ones, the EPA increases the likelihood that states will develop and implement appropriate control strategies in a timely and cost-effective manner allowing states to be correctly designated attainment or nonattainment in a timely manner. Furthermore, the new secondary standards are very poorly justified, not supported by quantitative data, and duplicative. First, the proposed secondary standard is based on subjective data. The EPA states that the secondary urban visibility impairment NAAQS is not health-based, but the proposal alludes to PM-related visibility health effects, such as stress or depression[12], to justify an adverse welfare effect that setting a new standard allegedly will rectify. The EPA has based its proposed secondary standard on *perceptions* and *attitudes* of an unnamed citizenry, who will all inherently have subjective expectations of acceptable visual air quality, rather than on objective ambient air monitoring data. The differences in citizen expectations appear to be linked to the ability to see objects at great distance and are related to the efforts to increase viewing distances under the Regional Haze Program. Under EPA's Regional Haze Program, it will take many years to improve regional visibility to "natural" levels (40 to 180 miles depending on the region). The TCEQ is skeptical that any secondary standard established based on subjective experiences could effectively address the real or perceived issues of urban visibility that could include haze and plume blight.

Secondly, the proposed secondary NAAQS may require states to develop control strategies designed to protect the public welfare in a manner that may be more stringent than those developed to protect the public health, since the proposed secondary standard is based on subjective data.

If the EPA proceeds with adopting a new secondary standard, the TCEQ recommends that the EPA adopt the surrogate approach proposed for new source review (NSR) permitting[13] into Appendix N as the method to demonstrate measured compliance with the standard. The technical analysis to support the surrogacy approach demonstrates that areas in attainment of the 24-hour primary $PM_{2.5}$ standards would also likely be in attainment of the proposed

[12] 77 FR 38973. Research has demonstrated that people are emotionally affected by low visual air quality, that perception of pollution is correlated with stress, annoyance, and symptoms of depression, and that visual air quality is deeply intertwined with a "sense of place," affecting people's sense of the desirability of a neighborhood (EPA, 2009a, Section 9.2.4).
[13] 77 FR 39025 to 39027.

secondary $PM_{2.5}$ visibility index standard.[14] This method would be used until the next PM review.

The TCEQ also recommends that the level should be at least 30 deciviews, to account for inconsistent value judgments, a great deal of spatial and temporal variability, and a very high level of uncertainty due to the lack of knowledge regarding the actual values of inputs to the visibility impairment analysis. This approach is advantageous because it would give EPA time to address the many technical challenges and uncertainties inherent in developing a new standard, as well as to determine which monitoring techniques will be utilized, as monitoring is preferred by the Clean Air Scientific Advisory Committee (CASAC).[15] For example, one technical challenge facing the EPA is a definition of an "urban" area on a national scale. Simply using regional haze *modeled* data as applied to "urban" areas to equate a national definition concerns the TCEQ for reasons mentioned previously, namely that unique background concentrations of air constituents and average relative humidity across different regions cannot be appropriately extrapolated to a national standard.

Third, the EPA's proposal related to the use of a light extinction indicator is inappropriate. The EPA proposes to use a new calculated $PM_{2.5}$ light extinction indicator, replacing the current primary $PM_{2.5}$ mass indicator. The EPA's approach, similar to that used in the Regional Haze Program (i.e., using an IMPROVE algorithm and associated equations to develop a deciview scale), is not an appropriate indicator to replace the current primary $PM_{2.5}$ mass indicator because the values proposed to be used are based on computer simulations and other techniques that adjust limited data rather than on ambient air monitored data. For example, in Texas the use of historical monthly, seasonal, or regional speciation averages for relative humidity is not appropriate if attainment status is based on daily values. The use of relative humidity values on gridded, 10-year average, monthly values[16] could lead to predicted rather than observed nonattainment for areas such as Houston.[17] Further, the procedures and equations for the secondary $PM_{2.5}$ visibility index NAAQS are unnecessarily complicated, fraught with uncertainty, and perhaps most importantly *not nationally representative*. The five major speciation components (sulfate, nitrate, organic mass, elemental carbon, and fine soil) are derived from reported concentrations of ammonium sulfate and nitrate ions, elemental carbon, aluminum, silicon, calcium, iron, and titanium and reported/adjusted concentrations of $PM_{2.5}$ organic carbon according to several conversion equations. Using the IMPROVE algorithm developed for the Regional Haze Program and developing adjustments and multipliers to the speciation components in an attempt to address regional differences to develop a national standard does not help.

Based on the high degree of uncertainty related to speciation components and a very high level of uncertainty due to the lack of knowledge regarding the actual values of inputs to the visibility impairment analysis, the EPA should continue to gather additional information before the next PM review to judge whether to re-propose a visibility impairment secondary standard rather

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[14] Kelly, et al. (2012) *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_td.html*
[15] 77 FR 38981, 38984.
[16] 77 FR 39047. The f(RH) value corresponding to each site-day shall be identified from the most recent 10-year average climatological database. This database contains spatially gridded monthly values of f(RH). The database record for the grid-point closest in distance to the monitoring site shall be selected for utilization in calculating $PM_{2.5}$ b_{ext}. The monthly value identified from the database record for the selected grid location will be the one corresponding to the sample month of the reported input speciation concentrations.
[17] 77 FR 38986. Footnote 174. The EPA staff noted that the R2 value (0.44) for Houston was notably lower than for the other cities.

than to propose it now. The EPA should use the Regional Haze Program, the $PM_{2.5}$ permitting program and other initiatives, and not the NAAQS, to effect changes in visibility impairment.

C. Data Handling

The TCEQ disagrees that a calculated visibility index should be used in comparison to the $PM_{2.5}$ visibility NAAQS. A direct measurement of light extinction should be used instead (77 FR 39003).

The EPA has proposed to use a calculated visibility index for comparison to the $PM_{2.5}$ visibility NAAQS because a suitable specification of the equipment or appropriate performance-based verification procedures cannot be developed in time for the review. The TCEQ disagrees that a calculated visibility index should be used in comparison to the $PM_{2.5}$ visibility NAAQS. A direct measurement of light extinction is a better approach to determine the visibility index because such measurement is an objective standard for regulators, industry, and the public, providing certainty for all throughout the regulatory process. Direct measurements would also allow for more sampling days, which would in turn provide a fully representative visibility index. A directly measured visibility index would also allow for development of appropriately tailored control strategies for each nonattainment area. A direct measurement of light extinction is also preferred by CASAC (77 FR 38983).

The TCEQ disagrees that historic monthly average relative humidity should be used in the visibility index calculation and believes that direct measurements of relative humidity should be used in the calculation instead (77 FR 39003).

The TCEQ disagrees that historic monthly average relative humidity should be used in the visibility index calculation. The TCEQ believes that a direct measurement, collocated with the PM or light extinction measurements, would better reflect the conditions in a specific area. Humidity can vary from hour to hour, and an average relative humidity value might not accurately represent areas that experience days with high relative humidity, such as the Houston-Galveston-Brazoria area. In a 24-hour period, which is the scale of the visibility index, the relative humidity can vary by over 50%. Using the measured relative humidity would be a better way to account for variability in relative humidity in the visibility index calculation.

The TCEQ requests that the instructions on calculating the visibility index for the secondary $PM_{2.5}$ NAAQS be written more clearly (77 FR 39003).

The TCEQ requests that the instructions on calculating the visibility index for the secondary $PM_{2.5}$ NAAQS be written more clearly. The instructions on how to calculate the visibility index are vague regarding the specific $PM_{2.5}$ speciation parameters used. Adding in parameter codes would allow for more ease when calculating the visibility index. In addition, the TCEQ requests that EPA prepare a data handling guide containing specific details on the calculation and parameter codes, including sample calculations.

The TCEQ recommends that the EPA include a mechanism in rule to address exceptional events related to relative humidity and other meteorological factors that could affect the compliance with the proposed visibility-based secondary standard.

The TCEQ realizes 40 Code of Federal Regulations (CFR) §50.1 and §50.14 reflect requirements in 42 United States Code (USC), §7619. In addition, we acknowledge the intent of Congress to assess compliance with standards based on measured exceedances of the NAAQS at an air

quality monitor.[18] As a result, the TCEQ contends that the EPA should base compliance and attainment on data measured at an air quality monitor. If the EPA adopts the secondary standard as proposed, there is nothing that limits the EPA's authority to consider factors unique to that standard. For example, say the EPA proposes to determine compliance using relative humidity based on gridded, 10-year average, monthly values. Therefore, EPA should amend 40 CFR §50.14 and the Appendix N to Part 50 rule proposal to require the use of actual monitored relative humidity and to allow for an exclusion of data shown to be related to relative humidity and meteorological factors and natural limits to visibility such as precipitation, clouds, fog, mist, smoke, and blowing dust.

D. Monitoring

The TCEQ disagrees with the placement of monitors used to represent long-term public exposure at near-road sites because the data are not representative enough to compare to a national standard.

In the preamble to the proposed revisions to the NAAQS for PM, the EPA states that the evidence linking the annual average exposure to adverse health outcomes is stronger than the evidence linking short-term exposure to the adverse outcomes. The EPA proposes that states use near-roadway monitors, which are nitrogen dioxide (NO_2) and carbon monoxide (CO) microscale or source-oriented monitoring sites, to represent long-term public exposure in residential, shopping, school, and employment settings. Such monitoring data are not representative enough of these settings to be used to compare to either an annual or a 24-hour national standard.

The TCEQ encourages the EPA to not set a requirement to use near-road monitoring sites for long-term maximum concentration $PM_{2.5}$ monitoring. Such near-road monitoring sites represent microscale, short-term pollutant exposures that would often grossly over-represent the annual average public exposure to a pollutant of long-term health concern such as $PM_{2.5}$. Even for the 24-hour $PM_{2.5}$ NAAQS, many near-road monitoring sites would be inappropriate because the public exposures in such locations are for only a fraction of a day with the rest of the day spent in neighborhoods with substantially lower $PM_{2.5}$ concentrations. In suggesting that data from near-road $PM_{2.5}$ monitoring is appropriate for NAAQS comparison and that additional data would be useful for increased understanding of various PM components near roadways as well as for epidemiological studies, the EPA is conflating monitoring to protect public health and monitoring associated with field research studies and epidemiological studies. In practice, regulatory monitoring is not usually adequate to support epidemiological studies; nor is a single monitoring station near a heavily traveled roadway adequate to describe the gradient of PM components with increasing distance from the roadway.

Using near-road sites is problematic because they are sited to be representative of short-term public exposures, on the time scale of the one-hour NO_2 and CO NAAQS, for *persons* living or *working near roadways*, such as in gasoline service stations, retail fast food outlets, convenience stores and many other settings, or commuting. Near-road sites are generally not intended to be representative of 24-hour or annual exposures in residential, school, or employment settings.

The TCEQ supports a requirement to operate a maximum concentration federal reference method (FRM), federal equivalent method (FEM), or approved regional method (ARM) in an area that represents the maximum concentration $PM_{2.5}$ exposure to residences or elementary

[18] 42 USC § 7619 b (3)(B)(ii)

schools. The monitors should be sited to represent maximum public exposure to PM on the time scales of the annual and 24-hour $PM_{2.5}$ NAAQS. The TCEQ supports the EPA's proposal to allow states to designate which FEM monitors are and which are not appropriate for comparison to the NAAQS. The TCEQ concurs that there are technical problems with some of these monitors that can make the data produced be unrepresentative of the actual PM concentrations at the site. In the alternative to using near-road monitors for the standard, states should be given the flexibility to use a maximum-concentration $PM_{2.5}$ NAAQS comparable monitor, if it is appropriate.

The epidemiological studies on which the EPA relies to propose the new $PM_{2.5}$ NAAQS used neighborhood scale monitors representing long-term public exposure in residential, shopping, school, and employment settings. The standards are being set based on such representative $PM_{2.5}$ monitoring data. Regulatory $PM_{2.5}$ monitors that produce data for comparison to the $PM_{2.5}$ standards should be similarly sited.

E. Implementation

The EPA should issue all implementation guidance in the form of an official implementation rule on which the public will have the opportunity to comment.

The TCEQ requests that the EPA provide proposed implementation guidance and tools as a formal implementation rule and with enough time to allow informed public comment. In general, the TCEQ will wait to comment until the EPA provides more information on implementation issues and specifically requests comment through public notice in the *Federal Register*. The TCEQ strongly suggests that the EPA hold stakeholder meetings in advance of any formal proposal to gather input for many of the hypothetical proposals and potential future rulemakings or guidance development that must be addressed to fully implement any new NAAQS.

The EPA should issue formal implementation guidance to address near-road nonattainment areas.

In addition to existing regulatory text, the proposed implementation rule should also include guidance on how to address nonattainment based on near-roadway monitoring. The EPA stated in the proposal that it plans to provide regulatory text similar to that of the existing implementation rule for the 1997 $PM_{2.5}$ NAAQS and will consider options for potentially updating certain policies in developing an implementation rule for the revised PM NAAQS. Guidance is necessary for states to effectively address near-road nonattainment areas. The issues states face are related to what control measures, apart from federally-required motor vehicle fleet standards beyond our control, are appropriate or effective for state and local agencies to take. The EPA should issue formal guidance on how to approach such implementation issues that arise when relevant regulatory nonattainment requirements are triggered by near-roadway monitors.

The TCEQ concurs with the EPA's proposed grandfathering provision for pending Prevention of Significant Deterioration (PSD) permit applications. The TCEQ also suggests that the EPA amend its policy requiring that any PSD permit issued on or after the effective date of a NAAQS must have a demonstration of compliance.[19]

The grandfathering provision is appropriate and should not include a sunset clause. Additionally, current EPA policy requires the state to implement a requirement in permitting that has not yet been adopted into the Texas SIP. The EPA should not burden SIP-approved states with the requirement to immediately develop permitting procedures to demonstrate compliance with a new NAAQS. Ideally, the EPA would promulgate in rule a phase-in period that would require the demonstration after implementation guidance and tools (including single-source models) are available.

The TCEQ concurs with using a surrogate approach to demonstrate compliance of the visibility-based secondary standard under the PSD program.

The TCEQ concurs with the approach to use the mass-based 24-hour $PM_{2.5}$ standard as a surrogate for the visibility-based secondary standard, notwithstanding our general disagreement with the necessity of the proposed visibility-based secondary standard. Further, the TCEQ suggests that the EPA codify the approach and its use in NSR permitting rules until such time that the EPA resolves any technical challenges including but not limited to, streamlining tools, single-source photochemical models, monitored speciation, evaluation of precursor emissions, and use of site-specific relative humidity values. At that time, the EPA should propose new rules to eliminate surrogacy with applicable grandfathering provisions.

The TCEQ does not agree with the use of the metropolitan area as the presumptive boundary for nonattainment areas for the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed secondary $PM_{2.5}$ visibility index NAAQS.

The determination of nonattainment area boundaries is not described in the proposal or in the 1997 $PM_{2.5}$ implementation rule, upon which the EPA states it will base the development of the implementation rule for the revised PM NAAQS. However, in the *National Air Quality Standards for Fine Particles: Guidance for Designating Areas (April 2003)*, the EPA stated that the Metropolitan Area should serve as the presumptive boundary for $PM_{2.5}$ NAAQS nonattainment areas, as follows.

- In Metropolitan Areas consisting of a single Metropolitan Statistical Area (MSA), the EPA presumes the entire MSA should be designated as nonattainment.
- In Metropolitan Areas consisting of multiple primary MSAs that collectively form a Consolidated Metropolitan Statistical Area (CMSA), EPA presumes the entire CMSA should be designated nonattainment.[20]

The TCEQ is concerned that the Metropolitan Area is too large an area to use as the presumptive boundary for nonattainment areas and prefers starting at the county boundary. In situations where PM may be a local issue, the TCEQ would like the prerogative to make the boundary smaller than that of the county. In the case of a local PM issue, the TCEQ considers requiring that the whole county be nonattainment to be an unnecessary economic hardship.

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[19] Stephen Page Memorandum, June 29, 2010, Guidance Concerning the Implementation of the 1-hour NO_2 NAAQS for the Prevention of Significant Deterioration Program

[20] EPA Memorandum, April 1, 2003, Designations for the Fine Particle National Ambient Air Quality Standards

The TCEQ agrees with the EPA's decision to not establish classifications for nonattainment areas for the proposed revised primary annual $PM_{2.5}$ standard.

The TCEQ contends that the establishment of classification categories for areas designated nonattainment for $PM_{2.5}$ is inappropriate at this time. FCAA, §172(a)(1) authorizes the EPA to establish classification categories for areas designated nonattainment for the primary or secondary PM NAAQS but does not mandate the EPA to act. In the past, the EPA has declined to include tiered classifications systems, namely with the implementation program for the 1997 and 2006 primary and secondary $PM_{2.5}$ standards. In the proposal, the EPA stated that it does not intend to establish tiered classifications for nonattainment areas for either the currently proposed primary annual $PM_{2.5}$ standard or for a revised primary 24-hour standard (if one is promulgated) (77 FR 39019 to 39020). The TCEQ supports the EPA's decision to not establish tiered classifications for $PM_{2.5}$ nonattainment areas. This decision provides a simplified implementation structure affording states the opportunity to flexibly implement control programs tailored to address emissions source mixes in each area with specificity.

The EPA should commit to firm deadlines for the proposed and finalized implementation rule for addressing the revised $PM_{2.5}$ NAAQS and revised monitoring regulations. Specifically, the EPA should commit to providing timely implementation guidance for reasonably available control technology (RACT) and reasonably available control measures (RACM) and FCAA, §110 infrastructure requirements.

The proposed rule for PM NAAQS includes background information on implementation guidance and provides general timelines for the proposal and finalization of an implementation rule to address any new implementation requirements resulting from the proposed revised primary annual $PM_{2.5}$ NAAQS and the proposed revised monitoring regulations (77 FR 39019). The TCEQ agrees with the EPA's general intent to propose this implementation rule within one year after the revised PM NAAQS are promulgated and finalize the implementation rule by no later than the time the area designations process is finalized (approximately one year later). However, the TCEQ requests that the EPA commit to firm deadlines for the completion of such implementation guidance documents rather than relying on "target dates." The TCEQ is specifically concerned with the timely provision of implementation guidance as it relates to RACT and RACM as well as FCAA, §110 infrastructure requirements.

Changes to the EPA's guidance on RACT and RACM for the proposed $PM_{2.5}$ NAAQS revision must be finalized early to avoid disrupting the states' SIP development process. An EPA memorandum dated March 2, 2012, entitled *Implementation Guidance for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)*, indicates that the EPA intends to revise guidance for RACT and RACM for the PM NAAQS. The TCEQ is also aware of a pending rule proposal (RIN 2060-AQ07) currently under review by the Office of Management and Budget (OMB) that will withdraw or revise certain prior determinations regarding RACT and RACM that were at issue with the 2007 implementation rule. If the EPA intends to change the guidance that states must use to evaluate RACT and RACM, the EPA must finalize that guidance before the beginning of the SIP development process. A state's analyses for RACT and RACM begin very early in the SIP development process and will typically need to begin more than a year before a SIP revision and associated rules are proposed for public comment. The EPA indicates (77 FR 39020) that it intends to finalize the implementation rule for the revised PM NAAQS at the same time as the final designations. If the EPA finalizes the implementation rule according to the schedule stated in the preamble, then states would have adequate time to adjust RACT and RACM analyses, if necessary.

In addition to providing timely guidance for RACT and RACM analyses, FCAA, §110 infrastructure guidance must also be provided early enough to assist states in preparing adequate infrastructure SIP revisions and allowing time for meaningful public participation. FCAA, §110 infrastructure SIP revisions are due to the EPA within three years after the promulgation of a NAAQS. FCAA, §110(a) includes a requirement that the states provide reasonable notice and opportunity for public hearing for these SIP revisions.

The preamble of the proposed rulemaking indicates that the EPA's "target date" for issuing infrastructure guidance would be no later than one-year after the revised PM NAAQS are finalized (77 FR 39019). This would allow for a reasonable amount of time for states to not only utilize the guidance to develop approvable infrastructure SIP revisions but to also allow for meaningful public participation.

The EPA has provided infrastructure guidance for previous NAAQS much too late for states to use the guidance to develop SIP revisions and still meet the three-year deadline. For example, the 2006 primary and secondary $PM_{2.5}$ NAAQS were promulgated on September 21, 2006, such that infrastructure SIP revisions were due September 21, 2009. However, the EPA did not issue final infrastructure guidance for the 2006 $PM_{2.5}$ NAAQS[21] until September 25, 2009, four days after the SIP revisions were due to the EPA. Similarly, the 2008 primary and secondary lead NAAQS were promulgated on October 15, 2008, such that infrastructure SIP revisions were due October 15, 2011. However, the EPA did not issue final infrastructure guidance for the 2008 lead NAAQS[22] until October 14, 2011, one day before the SIP revisions were due to the EPA. The 2010 SO_2 primary NAAQS was promulgated on June 2, 2010, such that infrastructure revisions are due June 2, 2013. As of August 2012, the EPA has not yet issued infrastructure guidance for the 2010 SO_2 NAAQS.

As a result of the EPA's lack of timely infrastructure guidance, states have been forced to expend effort and resources to develop SIP revisions without EPA guidance, and therefore may ultimately be wasting resources by developing submittals that will not be approvable. In order to meet statutory deadlines for submittal of infrastructure SIPs, states do not have the option of waiting for the EPA to provide guidance before proceeding with infrastructure SIP development, review, and submittal.

Overall, the EPA has routinely failed to issue timely implementation guidance for SIP revisions and to even meet statutory deadlines in the FCAA. As a result, the EPA has disrupted the SIP development process nationwide undermining the states' ability to submit sufficient SIP revisions meeting the EPA's expectations and requirements. The EPA should commit to finalizing the implementation rule for the $PM_{2.5}$ NAAQS at the same time as finalizing the area designations process and to finalize the infrastructure guidance one year after the revised PM NAAQS are finalized.

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[21] EPA. September 25, 2009. Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). Memo from William T. Harnett, Director, Air Quality Policy Division, Office of Air Quality Planning and Standards.
[22] EPA. October 14, 2011. Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS). Memo from Stephen D. Page, Director, Office of Air Quality Planning and Standards.

The EPA's FCAA, §110 infrastructure guidance should include detailed guidance on how states should address the interstate transport obligations in FCAA, §110(a)(2)(D).

Previous infrastructure guidance for the 2006 $PM_{2.5}$ NAAQS included "Guidance for Satisfying the Section 110(a)(2)(D) Requirement." This guidance indicated that technical analysis would be required to fulfill the requirements of §110(a)(2)(D)(i). However, this guidance did not specify how that technical analysis should be conducted or how the EPA intended to evaluate the analysis.

The issue is further complicated by the current status of the EPA's Clean Air Interstate Rule (CAIR) and Cross-State Air Pollution Rule (CSAPR). A December 2008 court decision found flaws in CAIR but kept CAIR requirements in place temporarily while directing the EPA to issue a replacement rule. In July 2011, the EPA finalized CSAPR to meet FCAA requirements and respond to the court's order to issue a replacement program. On December 31, 2011, the United States (U.S.) District Court of Appeals for the D.C. Circuit issued a stay of CSAPR pending judicial review. In its stay order, the court also directed the EPA to continue to implement CAIR while the case was under review. On August 21, 2012, the U.S. District Court of Appeals for the D.C. Circuit vacated CSAPR. Under the court's ruling, CAIR will remain in place until the EPA develops a valid replacement for CAIR. Therefore, all the requirements in CAIR are federally enforceable, and all sources that are covered by CAIR must continue to comply with the requirements of the program.

Although the September 25, 2009, infrastructure guidance indicated that states could not rely on CAIR for the 2006 24-hour $PM_{2.5}$ NAAQS because CAIR does not address that NAAQS, the program is still in place. States need detailed guidance from the EPA on how to address these programs in their infrastructure SIP revisions for the 2012 PM NAAQS and detailed guidance on how to complete a technical analysis that does not rely on these federal programs. The EPA should issue this guidance no later than one year after the revised PM NAAQS are finalized.

The EPA should extend the deadline to submit the secondary $PM_{2.5}$ visibility index NAAQS infrastructure SIP (77 FR 39018).

Under FCAA, §110(b) the EPA may extend the deadline to submit an infrastructure SIP submission for a new secondary NAAQS by up to 18 months beyond the initial three years. Due to the uncertainty in how the new secondary $PM_{2.5}$ visibility index NAAQS will be implemented, the EPA should extend the deadline for submission of this infrastructure SIP revision. This option will allow states the flexibility to either submit a single SIP revision to address both standards at the same time or to use the additional 18 months to develop a separate SIP revision for the secondary standard.

The TCEQ agrees that a reasonable further progress (RFP) demonstration should not be required for areas that are able to demonstrate attainment within five years but encourages the EPA to seek further flexibility in demonstrating RFP for areas that cannot demonstrate attainment within five years.

By implementing the proposed $PM_{2.5}$ NAAQS under Subpart 1 of the FCAA, the EPA has flexibility in determining how states can demonstrate RFP. In its implementation rule for the 1997 $PM_{2.5}$ NAAQS (72 FR 20586), the EPA indicates that nonattainment areas that successfully demonstrate attainment within the initial five-year attainment deadline need not submit an additional demonstration of RFP. The TCEQ agrees that since there would be so little time between the SIP due date and the attainment deadline (two years), it is unreasonable to expect states to submit such a demonstration.

For areas that are not able to demonstrate attainment within the initial five-year deadline, the EPA states in its proposed rulemaking and implementation guidance for the 1997 $PM_{2.5}$ NAAQS, that states must demonstrate "generally linear progress" from the base year through the attainment year. The TCEQ encourages the EPA to look for flexibility in its interpretation of how states can meet RFP. While RFP is generally defined in FCAA, §171(1) as "annual incremental reductions," there is no requirement in Subpart 1 that the emissions reductions be linear. The TCEQ suggests that the EPA look for alternative means of demonstrating RFP. For example, if a state cannot meet the initial five-year attainment deadline for a nonattainment area but can demonstrate through RACM that the area will meet the standard "as expeditiously as practicable," there may not be any need to show that the emissions reductions necessary to attain the standard will occur in a linear fashion.

The EPA should not prescribe the amount of reductions required for contingency.

In its implementation rule for the 1997 $PM_{2.5}$ NAAQS (72 FR 20586), the EPA indicates that states should provide for measures that will yield approximately one year's worth of emissions reductions necessary to achieve RFP for an area in the event that the area does not meet the attainment deadline or fails to meet an RFP milestone. Because the EPA is implementing the proposed $PM_{2.5}$ NAAQS under Subpart 1 of the FCAA, states are required only to include contingency measures; there is no specific emissions reduction requirement. To require emissions reductions from the contingency measures to equal one year's worth of emissions reductions necessary for RFP is arbitrary. States should have flexibility to determine what level of emissions reductions is appropriate for contingency measures since the matter is not explicitly addressed in the FCAA for pollutants implemented under Subpart 1.

F. Other

The risk of exposure to $PM_{2.5}$ to public health is overstated.

The choice of cities to include in the urban case studies within the Quantitative Risk Assessment results in overestimation of risk. The analysis states: "we can draw several inferences regarding the representativeness of the urban case studies. First, the case studies represent urban areas that are among the most populated and most densely populated in the U.S. Second, they represent areas with relatively higher levels of annual mean and 24-hour 98th percentile $PM_{2.5}$." Additionally, the chosen areas do not have a representative distribution of risk factors including heart attack, smoking, and baseline mortality rates (EPA 2010, 4.4.1). Figure 4-17 clearly indicates that the chosen urban areas represent the upper end of mortality risks within the U.S. and therefore overestimate the impact of proposed standards relative to the rest of the country, again implying that the proposed standards are more stringent than necessary to protect public health.

Estimated risk due to ambient $PM_{2.5}$ is implausibly large in some areas of the analysis. The Risk Assessment states that "the patterns of reduction in terms of percent change in $PM_{2.5}$ - attributable risk are very similar for a given urban study area across health endpoints." (EPA 2010, 4.2.2). However, close inspection of city-specific data across the available studies calls into question this analysis. For instance, risk reductions are calculated for two Texas cities, Dallas and Houston, despite the fact that the city-specific information indicates largely non-statistically significant associations between $PM_{2.5}$ and all-cause mortality for the region including these

cities[23]. An additional group confirms the lack of association between ambient $PM_{2.5}$ and premature mortality for Dallas and Houston (Franklin et al. 2007). It is not clear why risk is attributed to these two cities in Texas in light of this contradictory data.

Two specific areas of the Risk Assessment are particularly troubling. Table G-1 indicates that the numbers of deaths attributable to $PM_{2.5}$ exposure are implausibly large at 63,000 to 88,000. In fact, a member of the CASAC also commented on this issue[24]. Table 5-25 indicates that upon lowering the NAAQS, each individual will benefit from 16 years of additional life. In 2011, the EPA analysis concluded that the FCAA in its entirety only contributed a number of months in life extension (EPA 2011b). The value derived in the Risk Assessment is clearly unreasonable and stretches the bounds of credibility. Together, this information casts doubt on the validity of the Quantitative Risk Analysis that has been used to support lowering the NAAQS and suggests that it is not an appropriate basis for selecting the levels of the revised standards.

The estimated benefits of the proposed standards are overstated.

As the RIA requests "comments on this general approach to characterizing uncertainty as well as the specific uncertainty assessments," we provide the following comments that are specific to the RIA but have bearing on our interpretation of the proposed rule as well.

In estimating the benefits for the proposed revision to the PM standards, the analysis is not clear as to whether the Policy Relevant Background (PRB) or the Lowest Measured Level (LML) is used. EPA introduces the use of the term "lowest modeled levels," which is confusing. If this terminology is actually referring to the PRB (as it appears to be), then this usage in the calculation of benefits is inappropriate. As stated in the Quantitative Risk Analysis: "…estimating risk down to PRB would have required substantial extrapolation of the estimated C-R functions below the range of the data on which they were estimated. Therefore, we estimated risk only down to the LML to avoid introducing additional uncertainty related to this extrapolation into this analysis." (EPA 2010, 3.1.1) Therefore, it is inappropriate to use "lowest modeled" in lieu of LML.

The RIA asserts "in analyzing the current 15/35 standard (baseline), the EPA determined that all counties would meet the 14/35 standard concurrently with meeting the existing 15/35 standard at no additional cost. No incremental costs or benefits are associated with 14/35 and consequently, there is no analysis 14/35 in this RIA." (EPA 2012b, ES.2.5) However, this does not agree with the presentation of altered risk at 14 versus 15 $\mu g/m^3$ in the Quantitative Risk Assessment. This discrepancy should be resolved, and 14 $\mu g/m^3$ should be presented to the Administrator and the public as a viable policy option in addition to retaining the existing standard, which is also not considered.

The presentation of available data is limited and, in some cases, misleading.

In presenting the studies that support lowering the standard, the data has been "cherry picked" to show only positive associations (regardless of their statistical significance) and to exclude evidence that does not support the policy decision to lower the NAAQS. In addition to an extremely limited discussion of the available evidence, there is also misrepresentation of data published by multiple authors. Specifically, in Figures 1 and 4 of the proposed NAAQS, the

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[23] See additional information for region 1 from Zanobetti et al. in docket EPA-HQ-ORD-2007-0517. Results are statistically significant for only 3 of 28 monitors in Texas and 15 of 188 monitors throughout region 1.

[24] 3-8-10 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.

results for the Veteran's cohort (Lipfert *et al.* 2006), which has repeatedly found no association between $PM_{2.5}$ and premature mortality[25], have been represented as supporting a positive association between $PM_{2.5}$ and mortality. Similarly, although Enstrom (2005) has reported no association between $PM_{2.5}$ and mortality in a cohort of elderly Californians, the analysis indicates that this data too supports a positive association between $PM_{2.5}$ and mortality (RIA Table 5.B-10). Furthermore, for multiple other studies[26] Figures 1 through 4 of the proposed rule selectively present positive data without mention that particular timeframes or regions within these same studies did not show such trends.

There are errors in the RIA.

In Table 5-20 of the RIA, the calculation of benefits based on the expert elicitation data appears to be incorrect. If the lower bound included 0 for 6 of the 12 participants (Table 5-18), then how does the lower bound of monetized benefits on Table 5-20 not include 0 for all 6 of these participants?[27] In Table 5-27 of the RIA there appears to be a mistake in the estimate for 13/35 based on the Krewski *et al.* 2009 C-R coefficient: 1 plus 9 does not add up to 11.

The fraction of benefits that occurs in projected nonattainment areas has not been estimated.

In Section 5.7.4 of the RIA, EPA states "we have not estimated the fraction of benefits that occur only in counties that exceed the alternative standards." Without this information, it is simply impossible to interpret the benefits that would be realized by adopting the proposed standards. Furthermore, areas that are in attainment will not implement measures related to the proposed NAAQS and therefore should not be included in the estimated benefits. This point is also related to the inappropriate assumptions: (1) that the C-R coefficient for $PM_{2.5}$-attributable mortality is linear with no threshold; and (2) that benefits should be calculated for concentrations of $PM_{2.5}$ below the LML of the applicable epidemiology studies. Both of these points are discussed above.

There appears to be double counting of benefits across multiple rules.

The RIA states: "It is important to emphasize that the EPA does not 'double count' the costs or the benefits of our rules. Emission reductions achieved under rules that require specific actions from sources—such as MATS—are in the baseline of this NAAQS analysis, as are emission reductions needed to meet the current NAAQS. For this reason, the cost and benefits estimates provided in this RIA and all other NAAQS RIAs should not be added to the estimates for implementation rules." (EPA 2012b, ES.4). The TCEQ agrees that the benefits estimated in this RIA should not be added to the estimates for implementation rules. However, it is apparent that the benefits estimated for previous rules included in the baseline for this assessment (i.e. MATS, CSAPR, and others listed in Table 3-2) have not been adequately accounted for in this RIA. In EPA RIAs, $PM_{2.5}$-attributed premature mortality generally represents the vast majority of the quantified benefits (EPA 2011b). The benefits for EPA rules are generally calculated not only to the LML of the relevant epidemiological studies but also to the PRB, also referred to by EPA as "lowest modeled levels." Although this RIA asserts that "emissions reductions achieved under rules that require specific actions from sources – such as MATS – are in the baseline of this NAAQS analysis," it does not follow that the benefits have not been double counted as those benefits extend far below the baseline (i.e. 15 $\mu g/m^3$) down to the PRB.

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[25] Lipfert *et al.* 2000, 2003, 2006, 2006b
[26] Franklin *et al.* 2007, McDonnell *et al.* 2000, and Schwartz *et al.* 2008
[27] See estimates for experts D, I, and L.

History of Double-Counting of $PM_{2.5}$ Benefits in Non-$PM_{2.5}$ NAAQS

Background: In 2011, President Barack Obama issued Executive Order 13563, which states that agencies should strive to reduce regulatory requirements that are "redundant, inconsistent, or overlapping."

TCEQ has observed that EPA has established a practice of including $PM_{2.5}$ co-benefits in rules that do not directly address PM emissions. The EPA emphasizes that proposed rules will generate health benefits that exceed expected costs. However, close inspection of the associated RIAs reveals that a majority of those benefits are from reductions in $PM_{2.5}$ even for rules targeting substances other than $PM_{2.5}$. In this case, such reductions are termed "co-benefits" because they result from changes in $PM_{2.5}$ levels projected to occur coincidentally from efforts to reduce other types of air pollutants.

Table 1. Summary of $PM_{2.5}$ co-benefits in non-$PM_{2.5}$ NAAQS

Year	*RIA for Non-* $PM_{2.5}$ *NAAQS*	$PM_{2.5}$ *Co-Benefits are >50% of Total*	$PM_{2.5}$ *Co-Benefits are Only Benefits Quantified*
1997	Ozone NAAQS	X	
2008	Ozone NAAQS	X	
2008	Lead NAAQS	X	
2010	SO_2 NAAQS	X	>99.9%
2010	NO_2 NAAQS	X	X
2011	Ozone Reconsideration NAAQS	X	

Including $PM_{2.5}$ co-benefits in multiple non-$PM_{2.5}$ NAAQS is redundant.

FCAA, §109 requires that each NAAQS be set at a level that protects public health with "an adequate margin of safety" (i.e. a point where no additional public health improvements would be gained by tightening the standard any further). If those concentrations are safe, then it is not appropriate to calculate co-benefits for $PM_{2.5}$ below this level to justify non-$PM_{2.5}$ regulations. Moreover, co-benefits from any pollutant that is regulated as a criteria pollutant with a NAAQS that conforms to the requirements of the FCAA should not be included in the RIA of any other pollutant. Including $PM_{2.5}$ co-benefits in other RIAs not only results in double-counting of benefits but also prevents meaningful reductions in regulatory burdens while still meeting air quality objectives.

Baseline calculations for proposed rules are *inconsistent* with best practices.

The EPA has argued that it does not double-count the $PM_{2.5}$ benefits because it includes all existing regulations in the baseline of emissions for each of its RIAs for another rule; however, this is not the case for the following reasons: (1) multiple RIAs are prepared simultaneously creating a constant source of confusion and potential for double-counting; (2) review of the RIAs listed in Table 1 indicates that all applicable FCAA-related rules are not, in fact, included in the baseline calculations for these standards; and (3) the baseline calculations are based on monitored levels of $PM_{2.5}$. It is impossible to distinguish the effect of each rule on ambient levels of $PM_{2.5}$. Furthermore, each rule seeks to lower the same observed levels of ambient $PM_{2.5}$ resulting in double-counting of estimated benefits across multiple rules.

The consequences of *overlapping* rules include lack of transparency and miscommunication with the public and policy makers.

Quantification of $PM_{2.5}$ co-benefits are reported as part of the total benefits in the executive summary of an RIA and also in public announcements about the proposed rule. This creates confusion for audiences who often fail to realize that these benefits are mostly due to reductions in $PM_{2.5}$. Furthermore, $PM_{2.5}$-related benefits would be more effectively and appropriately obtained through revision to the $PM_{2.5}$ NAAQS than through non-$PM_{2.5}$ rules. Moreover, reliance on co-benefits undermines the practical value of RIAs and shields the EPA from pressure to improve its methods for characterizing and quantifying health and welfare benefits for pollutants it is charged with regulating.

The EPA should demonstrate a peer-review process that reflects transparency and commitment to representing all data, not just data that supports its policy goals.

The non-profit organization, Toxicological Excellence for Risk Assessment (TERA), provides a superb description of peer review:

> A peer review is an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology, and conclusions of the document under review…peer reviewers and consultants should be selected for both independence and scientific/technical expertise…[and]include a range of perspectives on each panel, including diverse professional affiliations (e.g., academic, consulting, environmental, government, and industry). The evaluation of real or perceived bias or conflict of interest is an important consideration and for both peer review and consultation panels and every effort is made to avoid conflicts of interest and biases that would prevent a panel member from giving an independent opinion on the subject…an objective evaluation by independent experts with a variety of different viewpoints and perspectives is critical to the credibility of any peer consultation or peer review.[28]

The TCEQ agrees with this description and strives to implement these principles. In fact, when the TCEQ revises its Guidelines for Risk Assessment, a peer review is conducted by a disinterested third party. No person on the peer review panel works for or receives funds from the TCEQ. It is a conflict of interest for such individuals to participate in the peer review process, although stakeholders are welcomed to participate in the public comment process. Following the public comment period, each and every comment is addressed and changes are made to the document (when justified) as a result of this process. When the TCEQ disagrees with a comment, justification is provided in the response to comment document, which is made publically available along with the modified Guidelines document. The EPA should utilize an equally transparent process free, as much as possible, of conflict of interest.

To this end, the following recommendations for improvement are suggested:

- Generally speaking, risk assessments that serve to inform cost benefit analysis should include the following steps.
  - Consider all available appropriate and relevant studies, not just studies that present positive results.
  - Report comprehensive weight-of-evidence based analyses, including positive and negative data.

[28] http://www.tera.org/Peer/Description.html

  - Perform extensive sensitivity analyses to determine how confounding affects the analysis.
  - Select health endpoints based on toxicological grounds rather than on post-hoc statistical grounds.
  - Focus on studies with exposure data collected for individuals instead of groups (i.e. the studies by Pope *et al.* 2002, Laden *et al.* 2006, and Krewski et al. 2009 do not determine personal exposure to PM – it was assumed to be equal for all individuals within a metropolitan area).
  - Use Cox proportional hazards models as the exposure-response models.
  - Do not use splines in statistical models, especially smoothing splines, as they have the effect of making the data fit the model instead of choosing an appropriate model to fit the data.
  - Consider including thresholds and nonlinear relationships in the exposure-response models.
  - Estimate risks using best estimates of individual exposure rather than extreme characterizations of population exposures.
  - Estimate risks for the general population in addition to the "most sensitive" subpopulation.
  - Clearly state the assumptions made and their qualitative and quantitative consequences.

- Emphasis should be placed on the limitations of the available scientific literature in order to provide policy makers with accurate information. This is particularly important to avoid the appearance that proposed rules are based on policy objectives and merely "backed up" by applicable scientific evidence.
- Members of the Science Advisory Board and CASAC should not include the authors of studies utilized in that specific assessment, nor should they be current recipients of EPA funding, as this represents a significant conflict of interest (see Figures 1 and 2). If such individuals are to be consulted, equal weight should be given to scientists representing a wide variety of backgrounds and points of view, e.g. local or state governments.
- Prior to developing a rule, the EPA should solicit stakeholder input during the development phase. The TCEQ has found that engagement of affected regulated entities can help avoid the need for drastic changes from proposal to final adoption of a rule.
- When soliciting public comment, the EPA should respond to each comment in a substantial manner and revise technical and policy documents accordingly. A response to comments document that lists each comment (acknowledging that there may be multiple comments with very similar objectives that can reasonably be combined for this purpose) along with the EPA's responses should be provided with every rule.
- Place the risks associated with ambient air pollution into the context of other risks people face. This function is a crucial responsibility of public health officials who have an obligation to present scientific data in an unbiased manner and avoid inaccurate or inflammatory language.

An apparent conflict of interest exists in recent EPA activities related to the hand-picking of experts.

Expert Elicitation: The EPA conducted an expert elicitation study to better "characterize uncertainty" in the relationship between fine PM and premature mortality[29] and now presents an array of information from this study in its analyses. This representation of the results for each of the 12 experts as well as estimates based on the most recent epidemiological-based estimates from the ACS study (Pope *et al.* 2002) and from the six-city study (Laden et al. 2006) and most recently, the updated analysis of the ACS cohort by Krewski et al. 2009 are included. The selection of experts and the composition of the panel is an area of concern. A number of the experts on the panel have decades of work invested in epidemiological studies showing an association between PM exposure and adverse health effects. For example, six of the 12 experts were co-authors of the ACS and HSC studies, which the EPA ultimately relied on to quantify PM mortality. Unfortunately, although asked to include studies that reported contradictory data, 6 of the 12 experts did not do so, and none of the authors of those studies participated in the expert elicitation. While one would expect such panels to include experts in the epidemiology field, the selection and composition of expert elicitation panels to assure an appropriate balance remains an area of continuing concern in applying expert elicitation methods to a quantitative uncertainty analysis.

CASAC Membership: A review of the membership of the chartered CASAC (Figure 1) as well as the PM review panel of the CASAC (Figure 2) indicates that most members are affiliated with academic institutions and receive EPA funding[30]. This information raises significant concerns regarding conflict of interest within the CASAC as well as undermining the goal of independent peer review of EPA rulemakings and associated analyses.

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[29] Industrial Economics Inc., 2006. Expanded Expert Judgment Assessment of the Concentration-Response Relationship Between $PM_{2.5}$ Exposure and Mortality. Final Report. September 21, 2006. Industrial Economics Incorporated. Cambridge, MA. Available at: http://www.epa.gov/ttn/ecas/ria.html see also Roman et al. 2008. An Expert judgment assessment of the mortality impact of changes in ambient fine particulate matter in the U.S. Environ. Scie. Technol. 42(7), 2268-2274.

[30] Information on membership was located on the CASAC webpage http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC and funding was found on the website for extramural research. A search was conducted for the name of each member of the chartered/PM panel. A designation of "EPA Funded" was determined if the individual was a recipient of either an individual or center grant or was listed as an author of a manuscript that acknowledged EPA funding. http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/search.welcome

Figure 1. Chartered Clean Air Science Advisory Committee (CASAC)

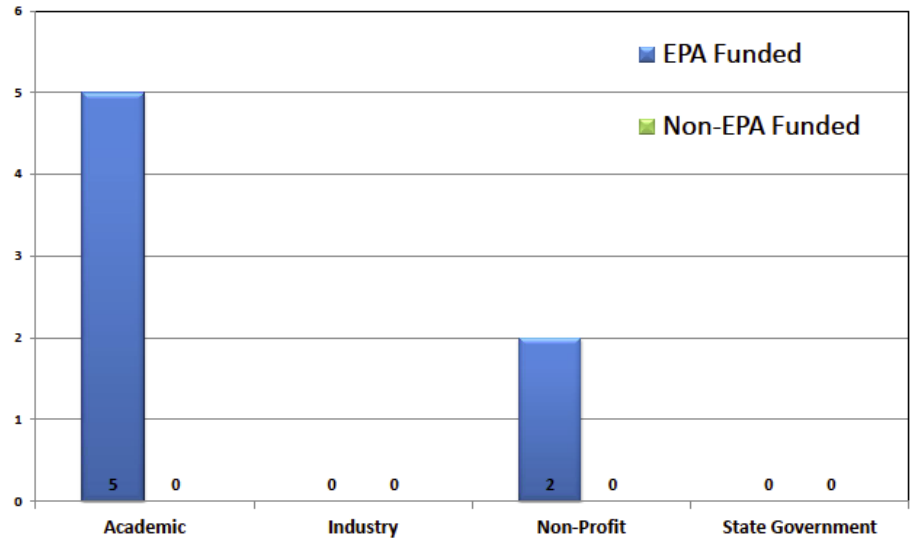
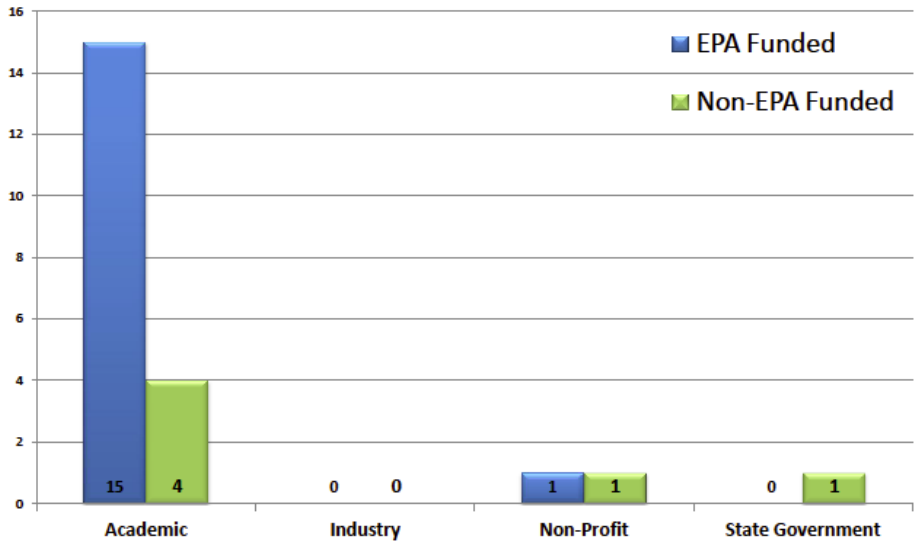


Figure 2. Particulate Matter Review Panel of the CASAC



The rule should state that the air quality index (AQI) will be based on primary NAAQS.

42 USC, §7619 (FCAA, §319) requires the EPA to establish a uniform AQI for reporting of air quality. While Congress' stated intent is to give the highest priority to protection of public health, it did not limit the AQI to the primary NAAQS. The EPA should address this concern in the rule to state that the AQI will be based on primary NAAQS.

The EPA should consider the states' obligation to have a minor source permitting program and resulting economic impact on small businesses when developing rules and implementation guidance.

The TCEQ respects the court's determination that the EPA does not need to determine if the NAAQS will have a significant economic impact on small businesses (entities), because establishing a NAAQS does not impose any direct requirements on them.[31] However, 42 USC, §7410 (FCAA §110) requires states to have a minor source permitting program,[32] and the states must consider costs when developing rules to implement the minor source program. Therefore, EPA should consider this SIP requirement when developing rules and implementation guidance and provide for exemptions in rule and streamlining techniques in the Guideline on Air Quality Models (40 CFR Appendix W to Part 51).

[31] The U.S. Court of Appeals for the District of Columbia ruling in American Trucking Associations, Inc., v. EPA that the states, not EPA, have direct authority to impose NAAQS implementation burdens on small business, and that EPA's proposed rulemaking does not have a direct impact on them.
[32] 42 U.S.C. § 7410 (a) (2) (C) and (D) and FCAA 110 (a) (2) (C) and (D).

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