UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Insert date

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Peer Review of EPA's *Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard*

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC), augmented by subject-matter-experts to form the CASAC Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQS) Review Panel (hereafter referred to as the panel, roster provided in Enclosure A) held a public teleconference on December 5, 2008 to review EPA's completed *Risk and Exposure Assessment (REA) to Support the Review of the NO_2 Primary National Ambient Air Quality Standard*. The panel provides comments, even though the draft provided is regarded as final in order to meet the schedule for NAAQS review. The CASAC, nonetheless, considered that it should review this draft, which represents the first instance of completing a REA under the revised approach for NAAQS review. Because this review was scheduled at the request of CASAC, specific charge questions were not provided by EPA.

Overall, the CASAC found this version of the REA to be satisfactory in its approach to moving from the scientific foundation developed in the Integrated Science Assessment (ISA) to setting out evidence-based options for the NAAQS. The REA provides the needed bridge from the evidence to a characterization of the exposures and associated risks with different profiles of exposure. It draws on toxicological and epidemiological evidence and addresses risk to an identified susceptible population, people with asthma. The REA also systematically described uncertainties associated with the risk assessments. The REA offers some general comments about the role of scientific evidence and policy judgments in revising the NAAQS. The CASAC offers the reminder that the NAAQS are evidence-based and that policy judgments are needed to cover gaps and associated uncertainties in the evidence base.

As the panel received the complete REA in stages, and has provided comments previously on at least the first 8 chapters, the current review focuses primarily on chapters 7 through 10, with a main objective of informing EPA on the appropriateness of

the conclusions in chapter 10 on the indicator, form, averaging time and level for a potential revision of the NAAQS for NO_2, given the scientific foundation for decision making set out in the previous chapters.

We note first that the recommendations in chapter 10 arise from three different analyses performed in chapters 7, 8 and 9. These are specifically (i) an approach based on air monitoring results and health benchmark exceedances in 18 cities throughout the United States (chapter 7); (ii) an approach based on more detailed exposure and health benchmark exceedance results in Atlanta (chapter 8); and (iii) an epidemiologically and exposure-response approach, based again in Atlanta (chapter 9). Our review previously considered the quality of the work underlying chapters 7 and 8, and we now turn to the methods and results of chapters 9 and 10; the fidelity with which the results of each approach are summarized for chapter 10; and how well the three approaches are integrated in drawing conclusions in chapter 10, including the impact of uncertainty on the answers produced through the three approaches and the degree to which final recommendations for the NAAQS are bounded by these three sets of analyses.

Given the greatly accelerated schedule for review of this final draft – an issue that is troubling to CASAC in regards to performing our statutory role – the panel chose to retain our earlier, individual panel member comments on chapters 1 through 8 in their original form, and to supplement these with additional attached comments. These earlier review comments are not repeated here. A review of chapters 1 to 6 in the final draft indicates that they have not changed appreciably in any way that would affect the conclusions in chapter 10. As a result, the current review does not provide comments on chapters 1 through 8, except to the extent they influence our assessment of conclusions drawn in chapters 9 and 10.

As to chapters 7 and 8, our review focused on whether the final draft contains any significant differences in numerical results that affect applications in chapter 10. Here it is evident that the final draft does contain substantial revisions to the material presented originally in chapters 7 and 8, at least in the quantitative magnitude of the size of the population affected by exceedances if not necessarily in the qualitative significance of the results as reflected in chapter 10. These differences are due in part to methodological changes, and in part to the fact that the final draft report contains estimates of daily maximum exceedances while the previous draft reported total number of one-hour exceedances (so N exceedances in a day counted N times in the average).

With regard to the analysis of exceedances in Atlanta alone (the second approach), the methodology used is approximately that of the earlier draft. As a result, the estimates of figures such as number of asthmatic-days exceeding a health benchmark are similar in the two documents. This similarity can be seen, for example, by comparing Figure 8-16 in the final draft against Figure 8-15 an earlier draft, where the figures of the latter are within 20% of those in the former (the final draft values being lower than those of the earlier draft, resulting from corrections to the methodology suggested in previous CASAC reviews of the REA). These differences do not substantively affect any of the conclusions in chapter 10.

The analysis of incidence of emergency room visits in chapter 9 employs a methodology identical in both reports and consequently the incidence results are the same. EPA has chosen in the REA to summarize the results as percent of the incidence attributable to NO_2 exposures, rather than as total incidence, which provides a more easily understandable summary conclusion as to the magnitude of health effects. However, it would be useful to see both total incidence and percent incidence in adjacent tables of the final draft, as both provide information of value in decision-making. This could be accomplished by bringing a few of the tables, such as Table 4-1, from the Appendices back up into the body of the final draft, especially since the text in the final draft mentions the incidence numbers but the reader must go to the Appendices to find these.

In addition, the results on incidence are summarized as average daily incidence, averaged over a year. This approach masks the seasonality of incidence, which can vary significantly throughout the year. There may be policy implications of such seasonal variations due to the capacity of the health care system to cope with periods of high incidence, and there may also be implications for the uncertainty in risk estimates. At the least, the REA should mention these issues and their potential implications for policy decisions.

Uncertainty analyses have been improving with the sequential revisions of the REA. While it still is not possible to place rigorous and quantitative uncertainty distributions around the key conclusions, the results of chapters 7, 8 and 9, and therefore of chapter 10 which relies on these chapters, now include at least substantial qualitative analyses of uncertainty. The major sources of uncertainty have been identified in all three of these chapters, and some assessments made of their origins and implications. In chapter 9 (the epidemiological approach), the REA also employs a reasonable system of assigning measures of the degree of uncertainty (low/medium/high); and the direction of bias (if any) introduced by a specific source of uncertainty has been noted. This is all useful information that can go into a full assessment of uncertainty. However, there is little to no discussion of the basis for the specific judgments made of the subjective degree of uncertainty, and so the CASAC cannot comment on whether these specific judgments are reasonable. We support the characterization of uncertainty but recommend that a fully transparent approach be used for designating the level.

There is a difference in the nature of the uncertainty analyses performed in chapters 7, 8 and 9. The useful format employed in chapter 9 is more qualitative, but summarizes the results in a way that is most relevant for subsequent decisions. By contrast, chapters 7 and 8 contain more quantitative analyses of uncertainty, although the degree of quantification varies significantly from factor-to-factor. The result is a somewhat unbalanced and disjointed exploration of the "space" of uncertainty, with for example a lot of detailed discussion of uncertainty due to fitting a distribution to data and almost cursory exploration of the effects of uncertainty in developing health benchmarks. Chapters 7 and 8 should end with tables similar to the one on uncertainty in chapter 9.

It is unlikely, however, that further development of these procedures is needed to serve the purpose of the REA, or that a fully quantitative, Monte-Carlo-style, uncertainty analysis is feasible given the time available for the assessment process. And in any

event, some of the results, such as those in chapter 9, have had quantitative confidence intervals placed around the estimates of incidence. These are admittedly conditional intervals (i.e. conditional on the choice of exposure-response model form and conditional on the air monitoring results used), but they are useful nonetheless and should be informative in decisions. In any event, we are pleased that the EPA authors have taken the previous comments of CASAC in regards to taking uncertainty into account in developing this most recent REA.

The choice of the Tolbert/Peel epidemiological study is reasonable, given EPA's decisions to give increased weight to North American studies and to use Atlanta for the exposure analysis. By and large, the REA uses and reports the results of the Tolbert at al. analyses appropriately. There is some discussion about the use of average baseline rates and some potential bias due to the potential influence of NO_2 exposures on actual incidence; this discussion could be extended to consider the seasonal patterns of both ED visits and NO_2 in Atlanta. The REA correctly discusses the pros and cons of using single and multi-pollutant models in several places; however, on p. 273, this discussion is not as well-balanced as elsewhere. In chapter 10 (p. 289-90; 308), emphasis is given to “central estimates” without indicating that several of these “central estimates” are not statistically significant. This description needs to be modified.

The REA applies the concentration-response function from the Tolbert study appropriately to Atlanta ambient data. The analysis in chapter 9 is, however, based on an implicit assumption that changes in ambient air levels associated with different NAAQS values will be approximately uniform in magnitude across the 5 counties of the city, or at least across the areas of most significant exposure. This assumption is a natural consequence of using a monitoring station result as the measure of exposure for what is in reality a complex spatial pattern, and should be acknowledged at some point in the chapter or perhaps in chapter 10. We understand that the analysis was limited by the way in which the epidemiological study characterized exposure through this monitoring station. If the spatial field of ambient air concentration is simply shifted up or down at all spatial points equally when a different NAAQS is introduced, this assumption will be valid. But where this uniform shift is not the case – and we are convinced it is not uniform – the assumption will be less valid. The contribution of this problem to uncertainty in the results of chapter 9, and to the implications for conclusions in chapter 10, is neither clear nor discussed. Having said that, we also note that a similar assumption is inherent in all of the approaches, and the epidemiology-based approach provides additional information that supports EPA's evaluation that a more protective short-term standard is needed to protect public health. And again, as in uncertainty analyses, the EPA authors have performed the task we set for them in previous reviews of this REA, at least using a study that is of acceptable quality.

In considering further the choice of the study by Tolbert et al. (2007), which is an update of Peel et al. (2005), we note that several epidemiological studies have examined the associations between ambient levels of NO_2 and respiratory health endpoints; the results of these studies have been mixed with a large majority of them finding a positive association. These results are buttressed by several human clinical studies, which under controlled exposures, find an association between NO_2 exposure and respiratory symptoms and lung function responses. The authors chose to consider studies conducted

in the United States and to consider a health endpoint that was unambiguously adverse, emergency department (ED) admissions. Six key studies were identified in the ISA; of the six, four considered multi-pollutant models, an important consideration given the relatively high correlations between ambient levels of NO_2 and other pollutants and the concern that NO_2 could be serving as a surrogate for other pollutants. Two of these four studies were undertaken in Atlanta, and two in New York City. The two Atlanta studies are related with one being an update of the other with additional years of data. One New York City study found mixed results for NO_2 and asthma admissions (positive and negative) depending upon the borough of New York studied. The second study reported statistically significant and robust associations between NO_2 and asthma, even in multi-pollutant models.

The REA analysis could have used any combination of these four studies; indeed it would be useful to consider some additional analyses based upon all four studies as a sensitivity analysis. Given the disparity of results, this would likely demonstrate a range of responses, at least for asthma, the only endpoint these studies have in common. The Atlanta analyses are clearly an appropriate candidate; they consider total respiratory ED admissions, as well as subsets of respiratory disease as asthma, whereas the New York studies focus on asthma. In addition the Atlanta analyses are based upon several years of data with over one million respiratory visits and thus have sufficient statistical power to detect a modest association with NO_2. The two Atlanta papers are based upon the same data set: Peel et al. examine the associations between NO_2 and ED admissions for 1/1/93 through 8/31/2000; Tolbert et al. extend the analyses through 12/31/2004. For total respiratory disease the results are similar in both papers, especially for single-pollutant models.

The multi-pollutant model results are qualitatively similar across the studies; hence, the REA correctly emphasizes the results of Tolbert et al. as they are based on a larger study population. Peel at al., however, present more detail in some respects that might be noted or considered in the REA. Peel at al. report single pollutant model results for several respiratory disease categories; associations between ED visits and NO_2 are significant for upper respiratory infections and for chronic obstructive pulmonary disease, but not for asthma or pneumonia. If risk analyses for asthma ED admissions form a primary basis for final recommendations in chapter 9, it would be important to consider the Peel et al. results in addition to the New York analyses (In some unpublished results presented at a conference poster, Peel et al. found a significant NO_2-asthma association in the warmer months, but no association in the winter months). Both Tolbert et al. and Peel et al. considered an *a priori* lag structure of a three-day moving average of pollution levels (average of 0, 1, and 2 day lags relative to ED visits). Peel et al. also present results for individual lags and show very similar significant results for NO_2 with lags 0 through 3 in single pollutant models. This similarity should be noted as it provides support for the REA's using the moving-average as the indicator of pollution in its analysis.

A key issue underlying the conclusions in chapter 10 is whether Atlanta is to be taken as representative of exposures and effects in other moderately large urban areas. The EPA justification for Atlanta is found in chapter 8, which reads "…Atlanta is roughly in the middle of the distribution with respect to estimated population and total roadway miles when compared with the other locations examined. Given that there are

attributes that go in both directions with respect to the influence of on-road and other mobile sources on the representativeness of Atlanta relative to the other 17 urban areas examined in the air quality analysis, the REA concludes that the Atlanta exposure estimates are likely representative of other moderate to large urban areas included in this comparison. The REA does recognize that the Atlanta exposure results are likely lower on a population-weighted basis compared to the largest urban areas such as Los Angeles, New York, and Chicago given the greater proximity of the population to mobile sources in these large urban areas."

Chapter 10 contains a direct response to a key policy question that was the basis for the existing NAAQS. The existing NAAQS was established based on the claim that "Retaining the existing standard would also provide protection against short-term peak NO_2 concentrations at the levels associated with mild changes in pulmonary function and airway responsiveness observed in controlled human studies" (60 FR 52874, 52880 (Oct. 11, 1995)). The CASAC supports the conclusion by the authors of the REA that health effects studies conducted since the existing NAAQS was established, and the results of the current REA under review, suggest that the existing standard, both in terms of level (0.053 ppm) and averaging period (annual) are not protective of human health in regards to short-term peak NO_2 concentrations. This conclusion is supported uniformly by the three approaches employed in the REA. In this regard, we do not fully agree with the statement on Page 284 that "(t)he way in which exposure and risk results will inform ultimate decisions regarding the NO_2 standard will depend upon the weight placed on each of the analyses when uncertainties associated with those analyses are taken into consideration." Instead, the decisions reached appear as independent of the analysis selected, even if the cause and degree of uncertainty may vary between the analyses. But these differences have more of an effect on research programs aimed at reducing residual uncertainty than on policy decisions.

On Page 286, the authors note competing uncertainties, or biases. The first is that AERMOD may over-predict upper percentile exposures, and the second is that the Atlanta case study may under-predict exposures in cities where near-road populations are more common. It would be helpful if the authors were to give a summary statement as to the degree to which this introduces significant uncertainty into the final conclusions of the REA. The CASAC are of the opinion that these two sources of bias are likely to roughly cancel each other and so are not the primary sources of uncertainty in drawing policy conclusions, again given the robustness of conclusions across the three approaches.

The authors also note that "(h)owever, to the extent that a decision regarding standard level emphasizes the general uncertainties associated with quantifying the contributions of NO_2 to respiratory effects in epidemiologic studies and uncertainties regarding the public health significance of NO_2-associated airway hyperresponsiveness (particularly at 0.1 ppm), a level as high as 0.2 could be supported." Apart from whether the CASAC agrees that a level of 0.2 ppm is appropriate, a topic we explore elsewhere in this letter, we note that the treatment of uncertainty in the causal connections between NO_2 exposures and effects is not quantified, and so it is not possible to use uncertainty as the basis for a specific magnitude of adjustment to the upper limit on levels to be considered (here, by a factor of 2). The lack of guidance provided in the document on

how the various sources of uncertainty and the associated magnitude of uncertainty influence any specific conclusions as to exposure and risk leaves the results open to selective use in policy decisions. We encourage the REA authors to provide more guidance as to conclusions in chapter 10 that are meaningfully uncertain and the direction of this uncertainty (whether it is likely to be for or against health protectiveness, or neutral).

A further key issue is whether the Atlanta study results (chapters 8 and 9) can be extrapolated elsewhere, or at least serve as representative results for a larger U.S. population. The ISA shows that results can vary from across studies. Indeed a consideration of the above-cited studies for asthma ED visits and NO_2 shows variable results. For this reason it would have been preferable for the risk assessment to consider additional studies as well; unfortunately the number of studies that consider NO_2 in both a single-pollutant and a multi-pollutant context is limited; nevertheless some consideration of the New York studies could be helpful and considered as a sensitivity/uncertainty analysis. Secondly the results of a specific study are tied to the characteristics of the study and the location in which the study is conducted. The REA points out several of these characteristics, but should also that the use of EDs can vary geographically. For some populations, emergency departments are a major source of healthcare, and it is unclear how Atlanta may differ from other metropolitan areas in this regard. Some consideration of billing records across metropolitan areas could help answer this question.

There is a fundamental issue, however, that is not discussed as well as it should in this chapter; namely, the issue of differences between exposures and monitored concentrations of NO_2. The document (and the ISA) notes that exposures are likely to be significantly higher near roadways, and monitors may not capture these high exposures. The first two approaches give greater consideration to this issue than the third. For the third approach (based upon an epidemiological study), this issue can influence both the interpretation of results and the consideration of the results in the analyses of alternative standards. There is some discussion of this issue on p. 300, but it is based upon comparisons of personal exposures and ambient monitoring results for extended periods of time (>24 hours). For a much shorter period of one-hour, these comparisons are likely to be of little value. Highest exposures likely occur when individuals are near roadways; it is unlikely that they remain outdoors near roadways for periods of 24 hours or more. Unfortunately there are no measurements of short-term personal NO_2 exposures that might better inform this issue. In the REA, adjustment is made to estimate peak levels near roadways from monitored levels. The need for this adjustment contradicts the statement made at the bottom of p. 300. This issue also identifies the need to expand the discussion of how to interpret the results from the epidemiological analyses in the context of standard setting. A related issue is that of where regulatory monitors are likely to be placed; if they are placed near major sources or where ambient levels are thought to be higher (e.g., near roadways), the discussion in chapter 10 would be different.

There are four attributes of the standard discussed in chapter 10. The REA and supporting evidence provide no support for any alternative to NO_2 as an indicator; hence the choice of this indicator is clearly justified. The ISA gives greatest support for a short-term standard, averaging time of one to 24 hours. Epidemiological evidence supports

both averages; clinical studies demonstrate responses for shorter periods of time. The REA suggest an hourly standard based largely upon the human clinical study results. Patterns of population exposure are also relevant. Individuals are much more likely to be exposed to outdoor levels of NO_2 for shorter periods of time than longer periods of time because most individuals spend less than 10% of their time outdoors; hence the probability of being exposed to a peak level is higher for shorter periods of time than when averaged over longer periods of time. Further consideration of potential exposures from the behavioral and activity-pattern literature would improve the discussion of this issue in the REA.

The discussion of the form of the standard vis-à-vis the 98th or 99th percentile issue is well-discussed and well-presented. More discussion could be given to the issue of using data over a 3-year period; no support for this time period is given in the document.

Because the ISA indicates that the evidence relating long-term NO_2 exposures to adverse health effects is judged to be "suggestive but not sufficient to infer a causal relationship" for respiratory morbidity, and decreased growth of lung function in children has been associated with annual average concentrations below the current standard, it is important to consider the potential impact of alternative short-term standards on annual average concentrations. The revised REA includes Table 10-3, which shows that one-hour standards $\geq$ 0.15 ppm would likely result in annual average concentrations in some cities that are higher than the current standard.

Finally the REA considers a range of levels for the NAAQS. The range is large (50-2000 ppb), but is appropriate for illustrating the potential impacts of alternative levels. The analyses are helpful, but could be more explicit with respect to the uncertainties associated with estimated impacts of alternative standard levels. The presentation of "central estimates" only, for example, on page 308 is potentially misleading, as those who set the standards should be aware of the full uncertainties associated with the estimated impacts of a standard.

Overall, chapter 10 represents an appropriate model for a closing chapter of a REA. EPA has responded to many earlier comments of CASAC calling for integration of information generated for both the ISA and REA that could be used to support policy decisions. A remaining – and major problem - with both chapters 9 and 10 is the persistent inconsistency of consideration of alternative one-hour concentrations. At times 50 to 300 ppb is the range under consideration and at other times it is 100 to 300 ppb. Also, there is shifting between ppm and ppb. Eliminating this inconsistency would improve the document and allow the reader to focus on conclusions rather than trying to understanding the basis for these differences. We ask that this problem be addressed in any final document, as this issue was raised in previous reviews, but remains uncorrected.

In closing, the panel noted that the final REA has satisfied the need for a document that can link the scientific foundation for the NAAQS review, provided in the ISA, to future presentation of evidence-based options for the NAAQS, which will be provided in EPA's Advance Notice of Proposed Rulemaking (ANPR), now scheduled for publication in January 2009. The CASAC recommends that the remaining REA

technical issues identified in this letter be addressed in the ANPR, so that the science supporting the options can be clearly outlined in that document. We look forward to reviewing the ANPR early next year.

Sincerely,

Dr. Jonathan M. Samet, Chair
Clean Air Scientific Advisory Committee

cc: Marcus Peacock, Deputy Administrator

NOTICE

This report has been written as part of the activities of the EPA's Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee independently chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC provides balanced, expert assessment of scientific matters related to issues and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the Federal government. In addition, any mention of trade names or commercial products does not constitute a recommendation for use. CASAC reports are posted on the EPA Web site at: http://www.epa.gov/casac.

Enclosure A

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
Oxides of Nitrogen Primary NAAQS Review Panel

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SCIENCE ADVISORY BOARD STAFF
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Enclosure B: Compilation of Individual Panel Member Comments on EPA's completed *Risk and Exposure Assessment (REA) to Support the Review of the NO_2 Primary National Ambient Air Quality Standard*

This enclosure contains final written comments of individual members of the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQS) Review Panel. The comments are included here to provide both a full perspective and a range of individual views expressed by panel members during the review process. These comments do not represent the views of the CASAC or the CASAC Panel.

Comments Received:

(Final individual comments to be added)