

Draft for Discussion by the CASAC Oxides of Nitrogen Primary NAAQS Review Panel at the public meeting on September 10 2008. This draft is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered CASAC



**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<sub>2</sub> Primary National Ambient Air Quality Standard: Second Draft*

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 meeting on September 9-10, 2008 to review EPA's *Risk and Exposure Assessment to Support the Review of the NO<sub>2</sub> Primary National Ambient Air Quality Standard: First Draft*. EPA requested that CASAC address charge questions listed below that fell into four categories (characterizations of air quality, health effects evidence and selection of potential alternative standards for analysis, exposure, and health risks). Panel consensus comments on how the ISA might be further strengthened appear below in the form of responses to the Agency's charge questions within those categories. Individual comments from CASAC panel members are enclosed in Enclosure

The purpose of the assessment is to communicate EPA's assessment of exposures and risks associated with ambient NO<sub>2</sub>. Overall, CASAC finds that the second draft assessment (??INSERT LANGUAGE HERE CHARACTERIZING THE OVERALL ASSESSMENT, PROGRESS SINCE LAST DRAFT, IMPORTANCE FOR NAAQS REVIEW?)...

Characterization of Air Quality (Chapters 2, 6, and 7)

1. *To what extent are the air quality characterizations and analyses technically sound, clearly communicated, appropriately characterized, and relevant to the review of the primary NO<sub>2</sub> NAAQS?*

1 The air quality characterizations, analyses, and uncertainty and variability discussions  
2 are generally improved, but in some cases additional clarification is needed. There are  
3 inconsistencies in the air quality metrics used in the analyses and those considered as  
4 alternative standards. The REA now focuses on short term, higher concentrations, both  
5 in terms of benchmark levels and alternative standards. These concepts, and their  
6 differences, should be clarified. Currently, the approach proposes using 98th and/or 99th  
7 percentile levels, but then switches between using the overall 98th/99th hourly value, the  
8 daily maximum and the annual mean among the various monitors in a city. These  
9 multiple metrics are confusing, and make some of the analyses less informative to setting  
10 a standard.

11  
12 The derivation and use of the on-road enhancement factor,  $m$ , needs to be  
13 strengthened, with improved documentation and more explicit comparison with  
14 observations. Staff should consider using different weightings over the range of  $m$  values  
15 employed, based on a strengthened uncertainty characterization). The discussion of the  
16 measurements upon which  $m$  are based needs to address how those measurements  
17 represent on- and near-roadway exposures. Similarly, additional discussion about how  
18 the monitoring network provides meaningful information for exposure analysis is desired.  
19 This should include a better characterization of vertical concentration gradients and how  
20 monitoring height might impact the relationship between observed levels and exposure.  
21 There is some concern that the importance of the biases associated with monitoring  
22 height and monitor interferences might be misinterpreted.

- 23  
24 2. *In order to simulate just meeting potential alternative 1-hour daily maximum*  
25 *standards, we have adjusted NO<sub>2</sub> air quality levels using the same approach that was*  
26 *used in the first draft to simulate just meeting the current annual standard. To what*  
27 *extent is this approach clearly communicated and appropriately characterized?*  
28  
29 3. *Because of the impact of mobile sources on ambient NO<sub>2</sub>, we have estimated on-road*  
30 *NO<sub>2</sub> concentrations. To what extent is the approach taken technically sound, clearly*  
31 *communicated, and appropriately characterized? Do Panel members have comments*  
32 *on the relevance of this procedure for reviewing the primary NO<sub>2</sub> NAAQS?*  
33

34 The approach for calculating the on-road concentrations is based on an empirical  
35 relationship with parameters derived from published monitoring studies conducted at  
36 various distances from roadways. It would add scientific credibility to this study to  
37 conduct an evaluation of this approach using an independent data set. For example, the  
38 maximum NO<sub>2</sub> concentration may not necessarily occur on the roadway because NO will  
39 become oxidized to NO<sub>2</sub> as the roadway becomes dispersed and mixes with the  
40 background ozone. The extreme of the NO<sub>2</sub> concentration distributions may occur in  
41 configurations such as street canyons that are not treated in the current analysis. If it is  
42 not possible to address such extreme situations in the current framework, this limitation  
43 should be explicitly stated and its implications on the uncertainties of the results should  
44 be discussed.

45  
46 The APEX model plays a central role in the exposure assessment and some  
47 evaluation of this model (or reference to a previous evaluation) would be useful.  
48

1 At present, the metrics provided to assess performance of AERMOD for  
2 Philadelphia are limited, and the information provided suggests performance might be  
3 satisfactory for two monitors but is extremely poor at the third receptor with  
4 underestimations on the order of a factor of 3 to 4. The evaluation should be more  
5 extensive, and the distributions (e.g., cdf's) of the AERMOD results should be compared  
6 with observations. The use of a homogeneous background to correct the AERMOD  
7 predictions does not correct the poor modeling of the spatial NO<sub>2</sub> concentrations across  
8 the area. Two approaches can be used to correct this perfidious modeling result (the two  
9 approaches could be used in combination): (1) a more complete emission inventory can  
10 be used for AERMOD to provide a better representation of sources in the vicinity of the  
11 receptor where concentrations are significantly underestimated and/or (2) the data fusion  
12 (i.e., combination of AERMOD modeling results and monitoring concentrations) is  
13 conducted by using the modeling results to interpolate among the three receptors.

14  
15 The fact that only the resident population is treated in the exposure assessment  
16 should be explicitly mentioned and an estimate of the commuting population who may be  
17 exposed in Philadelphia County during working hours for example should be provided.

18  
19 The cities for which there are sufficient data to perform a detailed analysis (similar  
20 to the Philadelphia analysis) should be identified. Be upfront as to what are the  
21 possibilities (how many cities, what fraction of the city, etc.) should be made explicit so  
22 we can actually provide informed advice.

23  
24 If the decision is made to use epidemiologic results, the REA will need to address  
25 co-pollutant issues. In particular, while the data is limited as to how NO<sub>2</sub> correlates with  
26 species such as EC, that should be highlighted.

27  
28 *4. What are the views of the Panel regarding the adequacy of the assessment of*  
29 *uncertainty and variability?*

30  
31  
32 Characterization of Health Effects Evidence and Selection of Potential Alternative  
33 Standards for Analysis (Chapters 3, 4, 5)

34  
35 *1. The presentation of the NO<sub>2</sub> health effects evidence is based on the information*  
36 *contained in the NO<sub>2</sub> Integrated Science Assessment. What are the views of the Panel*  
37 *on the overall characterization of the health evidence for NO<sub>2</sub>? To what extent is the*  
38 *presentation clear and appropriately balanced?*

39  
40 Chapter 3 covers susceptibility, describing the range of populations found to be  
41 susceptible, both to air pollution generally and to NO<sub>2</sub> specifically. The document would  
42 be improved by sharpening its conclusions. Clearly, one important overall finding is that  
43 a large number of people could be susceptible, when considering the full range of groups  
44 identified. On the other hand, the experimental and epidemiological evidence would  
45 appear to converge in finding that asthmatics are the most susceptible. The concept of  
46 vulnerability, as distinct from susceptibility, is introduced, and appropriately followed  
47 through.

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1 This draft REA appropriately reflects the NO<sub>x</sub> *Integrated Science Assessment* (ISA)  
2 in summarizing conclusions regarding the currently available health evidence related to  
3 NO<sub>2</sub> exposures. The choice to express the overall evaluation of the data on the major  
4 findings in terms of five levels of “confidence” is applauded, since a consistent  
5 application of this approach can bring a new level of rigor and consistency to this type of  
6 evaluation. The REA concludes that a “likely causal relationship” can be inferred from  
7 the data for short-term NO<sub>2</sub> exposure and adverse effects on the respiratory system at  
8 near ambient levels of exposure – and that the susceptible populations include subjects  
9 with asthma or airways hyperresponsiveness (AHR) and the young and elderly. The ISA  
10 and the REA conclude that there is suggestive, but not sufficient, data to infer a causal  
11 relationship between short term concentrations near those associated with ambient NO<sub>2</sub>  
12 exposure and cardiopulmonary mortality and between long-term NO<sub>2</sub> exposure and  
13 respiratory morbidity. The existing data are considered inadequate to infer the presence  
14 or absence of a relationship between long-term concentrations near those leading to  
15 ambient NO<sub>2</sub> exposure and overall mortality.  
16

17 The basis for the above conclusions should be more clearly defined in the REA,  
18 particularly in drawing linkages to the ISA. Both the ISA and the REA build on primary  
19 conclusions related to strength of evidence for causality. The ISA needs to have a full  
20 discussion of the application of the Hill criteria, as adapted by the Agency for its review  
21 process: strength of association, experimental evidence, consistency, biological  
22 plausibility, coherence, temporal relationship and the presence of an exposure-response  
23 relationship. The ISA should refer to each of these criteria and assess the data with  
24 respect to each for each of the major health outcomes considered. If done in the ISA, the  
25 causal conclusions could then be summarized in the REA with explicit reference to the  
26 ISA. It is not clear that the 7 criteria were consistently considered in coming to the final  
27 conclusions for the various health outcomes. Absent such in-depth analyses, the  
28 conclusions of the ISA and consequently the basis for the REA are weakened.  
29

30 This set of evaluations for NO<sub>2</sub> uses the five-level classification of strength of  
31 evidence for causation. On page 32, lines 1-3, the staff makes the judgment that it will  
32 focus on endpoints for which the ISA “concludes that the available evidence is sufficient  
33 to infer either a causal or a likely casual relationship”. This represents a decision that sets  
34 a precedent with regard to the level of evidence in support of outcomes that will be  
35 considered in the REA. Given the precedent-setting nature of the decision, clearer  
36 justification is needed.  
37

38 A remaining task for this document is to compare and synthesize the results of the  
39 assessments based on the epidemiologic studies and the human clinical studies. One  
40 challenge in accomplishing this is addressing differences in doses received in these two  
41 different contexts. Human clinical studies involve controlled exposures to NO<sub>2</sub>  
42 concentrations at the breathing zone of the subject while the epidemiology studies rely on  
43 a small number of fixed monitors that are commonly 4-5 meters above the ground and  
44 which do not necessarily represent the actual human exposure concentrations. The REA  
45 needs to consider the representativeness of NO<sub>2</sub> concentrations measured at this height  
46 for estimating personal exposures of the general population.  
47

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1 A stronger justification is needed to set aside the studies of indoor NO<sub>2</sub>. The stated  
2 rationale acknowledges that these studies focused on NO<sub>2</sub> alone to the extent possible and  
3 that the exposure situation indoors differs from that outdoors. On the other hand, the  
4 experimental literature is based on exposure to NO<sub>2</sub> alone as well. Given the emphasis  
5 placed on the human clinical studies, there does not appear to be a solid rationale for  
6 setting aside the studies directed at exposure to NO<sub>2</sub> from indoor sources.

7  
8 2. *The specific potential alternative standards that have been selected for analysis are*  
9 *based on both controlled human exposure studies and on epidemiological studies*  
10 *conducted in the United States. What are the Panel's views on the appropriateness of*  
11 *these potential alternative standards (in terms of indicator, averaging time, form, and*  
12 *level) for the purpose of conducting air quality, exposure, and risk assessments and*  
13 *on the rationale used to select them for that purpose?*

14  
15 In general, the bases for selecting the indicator, averaging time, form, and level for  
16 the NO<sub>2</sub> NAAQS are clearly stated. The averaging time of 1-hour is reflective of the  
17 duration of the experimental studies and the finding that there are adverse health effects.  
18 CASAC would recommend that consideration be given to exploring scenarios for the 24-  
19 hour averaging time as well.

20  
21 The proposed alternative form of the standard is considered appropriate. The REA  
22 should better define the strengths and weaknesses of using the 98<sup>th</sup> or 99<sup>th</sup> percentile form  
23 for the standard – including defining how the exposure distribution influences how well  
24 these parameters reflect both the magnitude and extent of high level exposures. The  
25 epidemiological studies that form the basis for the proposed alternative standards are well  
26 described in the REA. However, the REA should more clearly describe how controlled  
27 human exposures were used to establish or validate the proposed range for NO<sub>2</sub> analyses.

28  
29 With regard to level, the document provides a clear rationale for assessing a lower  
30 range extending to 0.05 ppm, with which CASAC agrees. The upper end of the range is  
31 quite reasonable, due to the experimental findings.

32  
33 The REA states that alternative long-term standards to the current annual value  
34 will not be considered. The REA does not establish that a short-term standard alone  
35 would be sufficient to meet the public health protection mandate of the Clean Air Act.  
36 Are there areas of the United States that would be in compliance with a short-term  
37 standard but not with a long-term standard? The REA needs a discussion of the utility of  
38 the current long-term standard for NO<sub>2</sub>. The REA should develop a scientific foundation  
39 for any decision regarding retaining or revising the long term NAAQS for NO<sub>2</sub>.

40  
41 Characterization of Exposure (Chapters 6 and 8):

42  
43 1. *To what extent is the assessment, interpretation, and presentation of the results of the*  
44 *exposure analysis technically sound, clearly communicated, and appropriately*  
45 *characterized?*

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- 1 2. *The second draft assessment document evaluates exposures in Atlanta. What are the*  
2 *views of the Panel on the approach taken and on the interpretation of the results of*  
3 *this analysis?*
- 4
- 5 3. *What are the views of the Panel regarding the adequacy of the assessment of*  
6 *uncertainty and variability?*
- 7

8 Staff provided an update on progress since Chapter 8 is still under revision. The  
9 Atlanta case study location is a reasonable one. The panel commends the responsiveness  
10 of staff and their ongoing consideration of adequate prediction of air quality. The  
11 strategies Staff have outlined to improve the modeling are likely to bring the model  
12 results closer to observed concentrations. There is some concern that the modeling  
13 approach may underestimate high exposures to residents who live near roads. We  
14 encourage Staff to include a clear characterization of biases and additional assessment of  
15 the predicted versus observed concentrations. Though not discussed at this meeting, the  
16 rest of the exposure modeling is expected to be similar to the first draft REA, which we  
17 previously commented on. The personal exposure data from Atlanta should also be  
18 compared with the model results.

19  
20 PERHAPS SAY SOMETHING ABOUT THE NEED FOR THE CASAC TO PROVIDE  
21 ADDITIONAL ADVICE ON THE FURTHER DEVELOPMENT OF THE EXPOSURE  
22 ASSESSMENT AT A FUTURE TELECONFERENCE?  
23

#### 24 Characterization of Health Risks (Chapters 7, 8, 9):

- 25
- 26 1. *Based on conclusions in the final ISA regarding airway responsiveness, we have*  
27 *expanded the range of potential health effect benchmark values to include 0.1 ppm.*  
28 *Do Panel members have comments on the range of potential health effects benchmark*  
29 *values chosen to characterize risks associated with 1-hour NO<sub>2</sub> exposures?*
- 30
- 31 2. *To what extent are the assessment, interpretation, and presentation of health risk*  
32 *results technically sound, clearly communicated, and appropriately characterized?*
- 33
- 34 3. *A focused risk assessment has been conducted for emergency department visits in*  
35 *Atlanta, GA. To what extent are the assessment, interpretation, and presentation of*  
36 *health risk results technically sound, clearly communicated, and appropriately*  
37 *characterized? What are the views of the Panel on the approach taken and on the*  
38 *interpretation of the results of this analysis?*
- 39
- 40 4. *What are the views of the Panel regarding the clarity and adequacy of the discussion*  
41 *of uncertainty and variability with respect to the characterization of health risks?*
- 42

43 The health risk assessment methodology described in Chapters 7 and 9 is well-  
44 developed and generally of high quality. The basis for expanding the range of exposure  
45 levels considered in the REA to include 0.1 ppm NO<sub>2</sub> is well-developed in the document.  
46 It is less clear, however, why a value as low as 0.05 ppm is not proposed, given results in  
47 the ISA. This decision should be more clearly justified, or the range expanded downward  
48 accordingly. At a minimum, 50 ppb and 100 ppb should be included in the Chapter 7

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1 exceedances tables (e.g., 7-5 thru 7-16) to allow comparisons across cities at relevant  
2 ambient conditions. On a related note, it would be more informative for the tables and  
3 discussion to include the rate of exceedances as well as the absolute number.  
4

5 The case for selecting Atlanta as the representative site for detailed exposure and risk  
6 calculations is not clearly made in the current version of the REA. An improved  
7 description of the rationale leading to this selection would improve understanding of the  
8 selection's implications. Justification for Atlanta's results being generalizable is needed,  
9 given the ultimate objective of assessing national health risks and the potential for  
10 possible recommendation of an alternate national air quality standard.  
11

12 The topics of uncertainty and variability are central to interpretation of the analyses in  
13 the REA. The presentation of these concepts throughout the document is uneven,  
14 repetitive, and lacking sufficient specificity. The discussion should highlight the most  
15 important and relevant sources of uncertainty and variability for the main analyses. Key  
16 points and issues should be addressed in the document, with supporting additional details  
17 located in appropriate appendices.  
18  
19

20 In closing, the CASAC was pleased to review this second draft of the *Risk and*  
21 *Exposure Assessment* for the primary NO<sub>x</sub> review. We look forward to reviewing the  
22 Advance Notice of Proposed Rulemaking in January 2009 and to continuing to advise  
23 you as you complete your assessment of the NO<sub>x</sub> primary standard.

24  
25 Sincerely,  
26  
27

28  
29 Dr. Rogene Henderson, Chair  
30 Clean Air Scientific Advisory Committee  
31

32 **Enclosures**  
33

34 Enclosure A: Roster of CASAC Oxides of Nitrogen Primary NAAQS Review Panel  
35

36 Enclosure B: Compilation of Individual Panel Member Comments on EPA's Risk and  
37 Exposure Assessment to Support the Review of the NO<sub>2</sub> Primary National Ambient Air  
38 Quality Standard: First Draft

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**Enclosure A**

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

**CHAIR**

**Dr. Rogene Henderson**, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

**CASAC MEMBERS**

**Dr. Ellis B. Cowling**, \* University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

**Dr. James Crapo**, Professor of Medicine, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

**Dr. Douglas Crawford-Brown**, Professor and Director, Department of Environmental Sciences and Engineering, Carolina Environmental Program, University of North Carolina at Chapel Hill, Chapel Hill, NC

**Dr. Donna Kenski**, Data Analyst, Lake Michigan Air Directors Consortium, Des Plaines, IL

**Dr. Armistead (Ted) Russell**, Professor, Department of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

**Dr. Jonathan M. Samet**, Professor and Chair of the Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**CONSULTANTS**

**Mr. Ed Avol**, Professor, Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

**Dr. John R. Balmes**, Professor, Department of Medicine, Division of Occupational and Environmental Medicine, University of California, San Francisco, CA

**Dr. Terry Gordon**, Professor, Environmental Medicine, NYU School of Medicine, Tuxedo, NY

**Dr. Dale Hattis**, Research Professor, Center for Technology, Environment, and Development, George Perkins Marsh Institute, Clark University, Worcester, MA

**Dr. Patrick Kinney**, Associate Professor, Department of Environmental Health Sciences, Mailman School of Public Health, Columbia University, New York, NY

\*Unable to participate in the May 1-2, 2008 CASAC Panel Meeting

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**Dr. Steven Kleeberger**, Professor, Lab Chief, Laboratory of Respiratory Biology, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC

**Dr. Timothy V. Larson**, Professor, Department of Civil and Environmental Engineering, University of Washington, Seattle, WA, USA

**Dr. Kent Pinkerton**, Professor, Regents of the University of California, Center for Health and the Environment, University of California, Davis, CA

**Dr. Edward Postlethwait**, Professor and Chair, Department of Environmental Health Sciences, School of Public Health, University of Alabama at Birmingham, Birmingham, AL

**Dr. Richard Schlesinger**, Associate Dean, Department of Biology, Dyson College, Pace University, New York, NY

**Dr. Christian Seigneur**, Vice President, Atmospheric & Environmental Research, Inc., San Ramon, CA

**Dr. Elizabeth A. (Lianne) Sheppard**, Research Professor, Biostatistics and Environmental & Occupational Health Sciences, Public Health and Community Medicine, University of Washington, Seattle, WA

**Dr. Frank Speizer**, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

**Dr. George Thurston**, Professor, Environmental Medicine, NYU School of Medicine, New York University, Tuxedo, NY

**Dr. James Ultman**, Professor, Chemical Engineering, Bioengineering Program, Pennsylvania State University, University Park, PA

**Dr. Ronald Wyzga**, Technical Executive, Air Quality Health and Risk, Electric Power Research Institute, Palo Alto, CA

**SCIENCE ADVISORY BOARD STAFF**

**Dr. Angela Nugent**, Designated Federal Officer, 1200 Pennsylvania Avenue, NW 1400F, Washington, DC, Phone: 202-343-9981, Fax: 202-233-0643, ([nugent.angela@epa.gov](mailto:nugent.angela@epa.gov))

1 **Enclosure B: Compilation of Individual Panel Member Comments on EPA's Risk and**  
2 **Exposure Assessment to Support the Review of the NO<sub>2</sub> Primary National Ambient Air**  
3 **Quality Standard: First Draft**

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(To be attached)