Compilation of Individual Panel Member Comments on EPA's second draft *Risk and Exposure Assessment (REA) to Support the Review of the SO_2 Primary National Ambient Air Quality Standard*

This enclosure contains pre-meeting comments from individual members of the Clean Air Scientific Advisory Committee (CASAC) Sulfur 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:

Comments from Dr. Ellis Cowling

Second Draft Risk and Exposure Assessment (REA) To Support the Review of the Primary National Ambient Air Quality Standard for SO_2

Very General Comments on the New NAAQS Review Process and Suggestions for Improvement in Development of Integrated Science Assessments and Risk and Exposure Assessment Documents

Before dealing with the details of my specific assignment during the April 16-17, 2009 CASAC Peer Review of the Second Draft Risk and Exposure Assessment (REA) for SO_2, I would like to offer a few general comments and suggestions for improvement of these periodic NAAQS Review processes and the changes that are being made in both the organization and focus of these reviews.

The Clean Air Act (CAA) of 1970 established two general goals for management of air quality in the United States -- protection of human health and protection of public welfare. Section 108 of the CAA directs the Administrator of EPA to identify and list "air pollutants" that "in his judgment may reasonably be anticipated to endanger public health and welfare " and to issue air quality criteria for those that are listed – hence the term "Criteria Pollutants."

As described on pages 1 and 2 of the Second Draft REA for SO_2, the CAA further directs the Administrator of EPA to "promulgate and periodically review, at five-year intervals, primary (public-health based) and secondary (public-welfare based) National Ambient Air Quality Standards for such pollutants. Based on periodic reviews of the air quality criteria and standards and promulgate any new standards as may be appropriate. The Act also requires that an independent scientific review committee advice the Administrator as part of the NAAQS review process -- a function now performed the Clean Air Scientific Advisory Committee (CASAC)."

A secondary standard, as defined in Section 109, must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air …" The welfare effects of concern include, but are not limited to "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

So far, the several Administrators of EPA since 1970 have:

1) Identified six specific "Criteria Pollutants" – carbon monoxide, ozone and other photochemical oxidants, sulfur dioxide, oxides of nitrogen, particulate matter, and lead – which have thus been designated officially as requiring development and implementation of National Ambient Air Quality Standards;
2) Emphasized protection of public health as the principal (and overwhelmingly important) *de facto* focus of concern within the Agency, and public welfare as a (rarely openly acknowledged) but distinctly less important *de facto* focus of concern;
3) Established Secondary (public-welfare-based) NAAQS standards for all six criteria pollutants that almost always were identical in form (including level, indicator, statistical

form, and averaging time) to the Primary (public-health based) NAAQS standards for each of these six criteria pollutants;

4) Developed a long-standing tradition of dealing with these six specific air pollutants mainly on a "one-at-a-time" basis rather than collectively – i.e., without strong attention to the frequent interactions and simultaneous occurrence of some of these pollutants as mixtures within the air in various parts of our country;
5) Maintained a reluctant attitude about the concepts of ecologically based "Critical Loads and Critical Levels" developed in Europe as possible alternative or additional approaches to air-quality management in the US; and
6) Maintained a long-standing general focus on the related concepts of:
   a) "Attainment counties and non-attainment counties,"
   b) "Attainment demonstrations" based on mathematical modeling of a limited number of exceedance events under extreme weather conditions, and
   c) "Local anthropogenic sources" as opposed to "both local and regional biogenic and anthropogenic sources of emissions."

In recent years, in contrast to several of the six ideas listed above, EPA has shown increased willingness to think more holistically – and in more fully integrated ways – about both the policy-relevant science and the practical arts of air quality management aimed at protection of both public health and public welfare. These shifts in both emphasis and approach have included:

1) Participation with other federal agencies and international bodies in discussions about the "One Atmosphere," "Critical Loads–Critical Levels," and "Multiple-Pollutant–Multiple Effects" concepts;
2) Adoption of the "NOx SIP Call" in 1999 and both the "Clean Air Interstate Rule" (CAIR) and the "Clean Air Mercury Rule" (CAMR) in 2005 with their more balanced perspectives about both regional (interstate) and local sources of emissions and interactions among NOx, SOx, VOCs, "air toxics," and mercury in the formation, accumulation, and biological effects of "ozone and other photochemical oxidants," and fine, coarse, thoracic, and secondary aerosol particles;
3) Recognition of both fine and coarse PM as complex and geographically variable mixtures of sulfate-, nitrate-, and ammonium-dominated aerosols; natural biogenic and anthropogenic organic substances; heavy metals including cadmium, copper, zinc, lead, and mercury; and some other miscellaneous substances;
4) More frequent discussion about of the occurrence and both ecologically-important and public-health impacts of mixtures of air pollutants; and, most recently
5) Making the unprecedented decisions (at least in the case of the NAAQS reviews for oxides of nitrogen and sulfur) to:
   A) Separate the preparation and review of documentation, the required CASAC and public reviews, and the final decision-making processes for the Secondary (public-welfare-based) National Ambient Air Quality Standards from the (previously always dominating) Primary (public-health-based) NAAQS review processes, and
   B) Prepare and publish a single draft plan for integrated [simultaneous] review of two different criteria pollutants (NOx and SOx), and
6) Identifying in advance a set of key "Policy-Relevant Scientific Questions" that are to be used as the primary focus of attention in the design and completion of all four major components of the new NAAQS review processes:
   A) The Integrated Review Plan (IRP),
   B) The Integrated Science Assessment (ISA),
   C) The Risk/Exposure Assessment (REA), and an operative
   D) Policy Assessment (PA) that historically has been developed in the form of an "EPA Staff Paper" and in the case of the last three Criteria Pollutant review processes (for

lead, ozone, and PM) were developed in the form of an "Advanced Notice of Proposed Rule Making (ANPR)."

[As all of us in CASAC are well aware, the recent NAAQS review for lead provided the first opportunity for CASAC to make a direct comparison between a PA developed in the form of an "EPA Staff Paper" and one developed in the form of an ANPR. In this particular case, CASAC found the Staff Paper much superior to the ANPR as a basis for setting NAAQS standards.]

All six of these adjustments in focus of attention, documentation requirements, and sequential procedures are being undertaken with the intention to:"

"… improve the efficiency of the process while ensuring that the Agency's decisions are informed by the best available science and timely advice from CASA and the public" … and

"… help the agency meet the goal of reviewing each NAAQS on 5-year cycles as required by the Clean Air Act without compromising the scientific integrity of the process."

Need for Policy Relevancy as the Dominant Concern in NAAQS Review Processes

In a May 12, 2006 summary letter to Administrator Johnson, CASAC Chair, Dr. Rogene Henderson, provided the following statement of purpose for these periodic NAAQS review processes.

> "CASAC understands the goal of the NAAQS review process is to answer a critical scientific question: "*What evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare?"*

During the past 3 years, CASAC has participated in reviews for all six criteria pollutants and has also joined with senior EPA administrators in a "top-to-bottom review" and the resulting recently-completed revision of the NAAQS review processes. These two experiences have led to a seemingly slight but important need for rephrasing and refocusing of this very important "critical scientific question:"

> ***"What scientific evidence and/or scientific insights have been developed since the last review that either support or call into question the current public-health based and/or the current public-welfare based NAAQS, or if alternative levels, indicators, statistical forms, or averaging times of these standards are needed to protect public health with an adequate margin of safety and to protect public welfare?"***

With regard to the important distinction in purpose of the primary (public health) and secondary (public welfare) NAAQS standards, it is noteworthy that in all five cases in which a secondary NAAQS standard has been established, the secondary standard has been set "Same as Primary."

Thus, a second very critical scientific question that needs to be answered for all six criteria air pollutants is:

> ***"What scientific evidence and/or scientific insights have been developed since the last review to indicate whether, and if so, what particular ecosystem components or other air-quality-related public welfare values, are more or less sensitive than the populations of humans for which primary standards are established and for this reason may require a***

different level, indicator, statistical form, or averaging time of a secondary standard in order to protect public welfare."

I hope these two "critical scientific questions" will be borne in mind carefully as CASAC joins with the various relevant parts of the Environmental Protection Agency in completing the upcoming reviews of both the primary and secondary National Ambient Air Quality Standards for SO_2 and, for that matter, also the other five Criteria Pollutants.

We now have the considerable advantage that a much more complete focus can be achieved in the Integrated Science Assessment than has historically been achieved in the encyclopedic Criteria Documents that have been prepared during the years since 1970.

Thus, several of us in CASAC have recommended that every chapter of the Integrated Science Assessment, Risk/Exposure Assessment, and the Policy Assessment documents for all criteria pollutants contain a summary section composed almost entirely of a series of very carefully crafted statements of Conclusions and Scientific Findings that:

1) **Contain the distilled essence of the most important topics covered in each chapter, and**
2) **Are as directly relevant as possible to the two Critically Important Scientific Questions written in bold italic type above**.

In this connection, I call attention once again to the attached "*Guideline for Formulation of Statements of Scientific Findings to be Used for Policy Purposes."* These guidelines were developed and published in 1991 by the Oversight Review Board for the National Acid Precipitation Assessment Program. They are the best guides that I know of for formulation of scientific findings to be used for policy purposes.

GUIDELINES FOR FORMULATION OF SCIENTIFIC FINDINGS TO BE USED FOR POLICY PURPOSES

The following guidelines in the form of checklist questions were developed by the NAPAP Oversight Review Board to assist scientists in formulating presentations of research results to be used in policy decision processes.

1) **IS THE STATEMENT SOUND?** Have the central issues been clearly identified? Does each statement contain the distilled essence of present scientific and technical understanding of the phenomenon or process to which it applies? Is the statement consistent with all relevant evidence – evidence developed either through NAPAP research or through analysis of research conducted outside of NAPAP? Is the statement contradicted by any important evidence developed through research inside or outside of NAPAP? Have apparent contradictions or interpretations of available evidence been considered in formulating the statement of principal findings?

2) **IS THE STATEMENT DIRECTIONAL AND, WHERE APPROPRIATE, QUANTITATIVE?** Does the statement correctly quantify both the direction and magnitude of trends and relationships in the phenomenon or process to which the statement is relevant? When possible, is a range of uncertainty given for each quantitative result? Have various sources of uncertainty been identified and quantified, for example, does the statement include or acknowledge errors in actual measurements, standard errors of estimate, possible biases in the availability of data, extrapolation of results beyond the mathematical, geographical, or temporal relevancy of available information, etc. In short, are there numbers in the statement? Are the numbers correct? Are the numbers relevant to the general meaning of the statement?

3) **IS THE DEGREE OF CERTAINTY OR UNCERTAINTY OF THE STATEMENT INDICATED CLEARLY?** Have appropriate statistical tests been applied to the data used in drawing the conclusion set forth in the statement? If the statement is based on a mathematical or novel conceptual model, has the model or concept been validated? Does the statement describe the model or concept on which it is based and the degree of validity of that model or concept?

4) **IS THE STATEMENT CORRECT WITHOUT QUALIFICATION?** Are there limitations of time, space, or other special circumstances in which the statement is true? If the statement is true only in some circumstances, are these limitations described adequately and briefly?

5) **IS THE STATEMENT CLEAR AND UNAMBIGUOUS?** Are the words and phrases used in the statement understandable by the decision makers of our society? Is the statement free of specialized jargon? Will too many people misunderstand its meaning?

6) **IS THE STATEMENT AS CONCISE AS IT CAN BE MADE WITHOUT RISK OF MISUNDERSTANDING?** Are there any excess words, phrases, or ideas in the statement which are not necessary to communicate the meaning of the statement? Are there so many caveats in the statement that the statement itself is trivial, confusing, or ambiguous?

7) **IS THE STATEMENT FREE OF SCIENTIFIC OR OTHER BIASES OR IMPLICATIONS OF SOCIETAL VALUE JUDGMENTS?** Is the statement free of influence by specific schools of scientific thought? Is the statement also free of words, phrases, or concepts that have political, economic, ideological, religious, moral, or other personal-, agency-, or organization-specific values, overtones, or implications? Does the choice of how the statement is expressed rather than its specific words suggest underlying biases or value judgments? Is the tone impartial and free of special pleading? If societal value judgments have been discussed, have these judgments been identified as such and described both clearly and objectively?

8) **HAVE SOCIETAL IMPLICATIONS BEEN DESCRIBED OBJECTIVELY?** Consideration of alternative courses of action and their consequences inherently involves judgments of their feasibility and the importance of effects. For this reason, it is important to ask if a reasonable range of alternative policies or courses of action have been evaluated? Have societal implications of alternative courses of action been stated in the following general form?:

"If this [particular option] were adopted then that [particular outcome] would be expected."

9) **HAVE THE PROFESSIONAL BIASES OF AUTHORS AND REVIEWERS BEEN DESCRIBED OPENLY?** Acknowledgment of potential sources of bias is important so that readers can judge for themselves the credibility of reports and assessments.

My Assignment in this CASAC Peer Review of the Second Draft Risk and Exposure Assessment (REA) for SO_2

My specific assignments for review of the Second Draft REA for SO_2 were to examine those aspects of Chapters 6 and 8 that relate to "Characterization of Exposure." This same assignment was also given to my CASAC colleague Ted Russell whose is even more experienced than I am with regard to "Characterization of Exposure" to gaseous and particulate forms of sulfur compounds in the ambient air – both through direct measurements of air concentrations and through modeling analyses of spatial and temporal variability in exposure to sulfur compounds. Thus, I am looking forward very much to Ted's responses to the same five Charge Questions outlined in Lydia Wegman's letter to March 20, 2009 to Angela Nugent.

As I began my examination of this Second Draft REA for SO_2, it was a pleasure to find that pages 4 and 5 in Chapter 1 do indeed contain a list of 10 very detailed "policy-relevant questions" that relate directly to the issue of the adequacy or inadequacy of the existing primary NAAQS for SO_2 to protect humans from the adverse health effects of ambient sulfur dioxide. These 10 questions relate very well within the framework of the general purposes of these NAAQS reviews as outlined earlier in these individual comments:

> ***"What scientific evidence and/or scientific insights have been developed since the last review that either support or call into question the current public-health based and/or the current public-welfare based NAAQS, or if alternative levels, indicators, statistical forms, or averaging times of these standards are needed to protect public health with an adequate margin of safety and to protect public welfare?"***

The next step in my review was to examine each of the 10 Chapters of this REA document hoping to find summary statements of "Conclusions and Scientific Findings" that could guide my thinking about many of the myriad of important topics covered in each of these 10 Chapters – and especially the five Charge Questions that Ted Russell and I had been asked to review. As indicated above, I was very please to find that bulleted summary statements of conclusions and scientific findings were provided:

1) In the form of 10 summary statements of "policy-relevant questions" in the "Introduction" of Chapter 1; these same 10 "policy-relevant questions were also repeated in the "General Approach" part of Chapter 10.
2) In the form of two separate lists and a detailed table (Table 4-1) on "Weight of Evidence for Causal Determinations" in the "Introduction" of Chapter 4,
3) In the form of five "Key Observations" listed at the end of Chapter 7, and
4) In the form of a detailed list of 13 "Key Uncertainties" and also five "Key Observations" listed at the end of Chapter 9.

In all the other Chapters and three Appendices, however, it was necessary to slog through the text, figures, and tables and thus find out for myself how to separate the proverbial wheat" from the "chaff" and then try to draw logical inferences regarding the important Conclusions and Scientific Findings that need to be drawn from the large body of scientific information covered in the remaining five Chapters of this REA document

(Chapters 2, 3, 5, 6, and 8) – which, perhaps by chance, included the two chapters (6 and 8) that I was assigned! With these general remarks in mind, let me turn to my specific assignments and the 5 Charge Questions that both Ted Russell and I were asked to address.

In the paragraphs below, please note my individual responses (written in normal type) following each of the five Charge Questions (**written in bold type**) for my particular parts of these two chapters as provided in Lydia Legman's March 20, 2009 transmittal letter to Angela Nugent.

1. **Does the Panel view the results of the exposure analyses to be technically sound, clearly communicated, and appropriately characterized?**

   Yes, in my opinion (as a mostly public-welfare savvy but a not so experienced public-health savvy research scientist), the exposure analyses described in Chapters 6 and 8 appear to me to be technically sound and appropriately characterized. My major concerns with regard to clarity of communication have to do with my inability to figure out what is meant the frequently used term "public health benchmark values." Although this term is used in many places throughout this REA document, and seems to be very important, I have no idea what is meant by what I suppose may be either a "term of art" in the medical science literature, or a specialized term used in EPA NAAQS review documents.

2. **The second draft REA evaluates exposures in St. Louis and Gene County, MO. What are the views of the panel on the approach taken to model SO_2 emission sources?**

   The approach taken in efforts to model SO_2 emissions sources, dispersal, transport, and air-concentration exposures in and around the City of St. Louis, MO and the much less densely urbanized area of Greene County, MO appear to be very similar to those used in the Southern Oxidants Study's 1993 through 2003 ozone and PM exposures in the areas surrounding Atlanta, Georgia and Nashville Tennessee in which I served as an important leader. Thus, the modeling approach taken in this REA document appear to be generally appropriate for the kinds of analyses needed to understand spatial and temporal variability in exposure to gaseous SO_2 and particulate sulfate within the two Metropolitan Statistical Areas in Missouri that were selected for exposure determinations in this REA.

   To what extent does this approach help to characterize the public health implications of the current standard? Does the panel have technical concerns with this approach?

   I have only very limited experience in the field of public-health assessments, and thus have no special competence with which to offer an informed judgment about the "public health implications of the current PM standards."

3. What are the views of the panel regarding the approaches taken to model SO_2 emissions sources?

See comments in response to Charge Question 2, above.

4. What are views of the Panel regarding the adequacy of the assessment of uncertainty and variability? To what extent have sources of uncertainty been identified and the implications for the risk characterizations been addressed? To what extent has variability adequately been taken into account?

Both uncertainty and variability in with regard to exposure estimates seem to have been covered pretty well. With regard to the implications of variability and uncertainty for health risk characterizations, however, I must admit to having only very limited experience and thus have no special competence with which to offer an informed judgment.

5. What are the views of the Panel regarding the staff's characterization of the representativeness of the St. Louis and Greene County, MO exposures and risk estimates?

Judging from the kinds of analyses and interpretations that we had to make in making decisions about "where to go next" after we completed our two-year-long Southern Oxidants Study investigations of ozone and PM production and accumulation in the 17 counties surrounding the Atlanta metropolitan area and the 11 counties surrounding the Nashville, Tennessee metropolitan area, it seems to me that EPA staff have done a very adequate job of determining the representativeness of the St. Louis and Greene County Missouri areas for the purposes of establishing National Ambient Area Quality Standards for SO_2 – recognizing, of course, that there are not very many urban and nearby suburban areas where both long-term and very short-term SO_2 monitoring data of adequate quality are available.

One additional point not related to the issue of Characterization of Exposure

The "history" part of Chapter 1 makes clear that the 1996 suit brought by the American Lung Association and the Environmental Defense Fund after the 1996 review of the SO_2 primary NAAQS standard regarding the need for a short term (e.g. 5-minute) NAAQS standard, led to a decision by the District of Columbia Court of Appeals that EPA had "failed to adequately explain the rationale for its decision NOT to promulgate a 5-minute standard."

Chapter 7 is the part of this REA document where 5-minute exposures are given relatively thorough attention. But the explanatory parts of Chapter 10, where the difficulties of establishing and implementing a five-minute exposure NAAQS standard are described, make me wonder if EPA may not come across once again as not giving a really adequate explanation of its reasons – if, it decides, once again, NOT to promulgating a 5-minute kind of NAAQS standard for SO_2.

Comments from Dr. Douglas Crawford-Brown

Review of the Risk and Exposure Assessment document for SO2

Douglas Crawford-Brown

This review is formed entirely around the charge questions, or at least the ones I felt competent to answer. I will note at first, however, that this was an impressive analysis by the EPA staff, covering an array of health measures that will inform regulatory decisions. The authors have focused attention onto the most significant health metrics and have produced an assessment that is consistent with the primary conclusions of the ISA. While quite long, the document is fairly easy to follow due to a good scheme for organization, with the reader able to skip over sections where they have insufficient expertise to move on to later sections, all without loss of information that will prove crucial later. This is due in large measure to a clear separation between steps in the assessment. There is also a good discussion, and science-based recommendations provided, for the form, averaging time, indicator and level.

I note also that this document addresses the most significant concerns raised by the CASAC in the previous draft review. I won't speak for other CASAC members, who understand their own initial concerns better, but at least in the case of my own concerns, these have either been addressed directly or have gone away due to the reorganization of the material.

I now turn to the specific charge questions:

Air Quality:

1. I will leave this to others with more expertise in this area. I do note that I found it simple to follow the assessment here, and that it was consistent with the findings of the ISA.

2. My view here remains as it was in the first draft: that I believe the methodology is computationally sound but results in a simulation that will have little relationship to actual exposures that will occur. But as this is a scenario assessment, and not an assessment of actual historical exposures, I am comfortable with the methodology. At the least, I cannot propose a methodology that would be better (only different). So, I support the use of this methodology.

3. I will leave this to others with more expertise in this area.

4. I believe the authors have responded adequately to concerns raised in the first draft. There is still no real nested variability/uncertainty analysis to provide quantitative estimates of the PDFs for both distributions. But the report identifies the major sources of each; gives at least a qualitative and at times a semi-quantitative estimate of the impacts of different variables; and helps the reader understand which are significant and which

are less so. The reader is provided a les detailed and systematic view of variability than of uncertainty, but it is probably as far as that component can be quantified. I am inclined, therefore, to say the EPA staff has done enough work on this topic to satisfy regulatory needs.

Health Effects Evidence

1. I found this section good on all counts. It properly reflected the findings of the ISA, and the summary was sufficiently short and concise to focus attention onto those effects and subpopulations that would form the basis of the health risk assessment. I see no evident bias in the presentation, or in its use in subsequent calculations.

2. I feel this selection is adequate and well explained. There are many different values that could be assessed, but the ones chosen cover the "space" of such values adequately for later regulatory decisions. I would not propose a more detailed mesh across these values as it is unlikely that there will be discontinuities in the region between any two alternative scenarios assessed.

Characterization of Exposure

1. There are two kinds of assessment conducted here: one based on air quality compared against benchmarks, and one based on APEX styles of assessment. In regards to whether air quality has been adequately simulated, I have to leave that to others with more expertise in the interpretation of monitoring results. I found it rather easy to follow the argument in the document, and to understand the results that were presented, but I don't know enough about this issue to have recognized gaps that might have existed or alternative and better ways to interpret the data. On the larger assessment rooted in APEX, however, I found the discussion easy to follow and the computational steps to be current state-of-the-art. My concern remains, as in all past reviews, that this level of detail in the assessment may go beyond the capacity of the scientific community to produce accurate depictions of exposure and risk, but even with the caveat I note that the authors have applied the methodology correctly and summarized results clearly.

2. I will need to leave this to others with more expertise on city and region-specific ambient air concentrations. However, the rationale for the selection is at least cogently presented.

3. I will leave this to others with more expertise in this area.

4. I found this part of the assessment to be less than fully informative, but probably about as far as things can be pushed at the moment. This a very complex set of assessments, and so there will naturally be some mixture of quantitative and qualitative methods. The current uncertainty and variability analyses succeeds in pointing the reader to most significant sources of U/V and giving a sense of both the direction and magnitude of impacts on the final risk numbers. That is about as far as we can push this issue at present. I would have liked to see a little more quantification of the impact of specific

sources of uncertainty on key results such as numbers of days with an exceedence, but I also am not convinced that such information would prove determinative or even especially useful in setting standards.

5. I will leave this to others with more expertise in this area.

Health Risks

1. I am fully comfortable with this range as it stands. It is likely to include the values to be considered in regulatory decisions, and I am unconvinced of effects at below 100 ppb (which doesn't mean they don't exist, only that I think the uncertainty in their existence is too large at these lower levels).

2. I found the health risk characterization to be well developed and clearly explained. It is a bit overwhelming to go through such a large body of results and try to find a consistent and compelling story to tell in a way that will guide later decisions. But at least all of the information is there and the authors have provided some summary remarks that help set the stage for subsequent decisions. The problem with having such an array of information to digest is that decision-makers are left somewhat free to focus on the results they want to use, rather than those the scientific community judge to be most sound as a basis for public health protection. But again, the authors have provided summary conclusions that will help guide this process.

3. I am completely comfortable with the methodology and the results generated, as it is a methodology we have seen applied in a number of these NAAQS assessments. I continue with my reservation that such a detailed assessment may be somewhat outside my comfort zone given the existing state of the science, but there is no step in the assessment at which I would say a debilitating error or approximation has been introduced. I simply note that such assessments require some pretty specific simulations of human behaviour within the ambient air concentration field, and I am sceptical of our ability to specify these behaviours fully. So long as we recognize that these are simulations of scenarios rather than actual human populations – and that is all we can do at the moment – then I am comfortable with the methodology.

4. My comments here are the same as earlier, although amplified by the fact that this part of the document integrates information from all of the sections and, hence, the problems in uncertainty characterization are even more pronounced. This document doesn't come close to a fully quantified nested U/V analysis, but I don't believe that would have been feasible anyway. As in other sections, I came away understanding where the authors believe the major sources of U and V are located, and with some idea of the magnitude and direction of uncertainty introduced by each variable or model. That is all I would expect at the present.

Policy Assessment

1. I was pleased to see this section in the report. It does exactly what one would hope from such a chapter: summarize the information at a level of detail and resolution sufficient for the policy side to pick up and run through to a decision. I was looking for a bit more specificity on the policy implications in the chapter, but would also understand if the EPA's argument is that this would be outside the remit of an REA. At the least, this chapter helps bound the range of information the decision-maker must reflect on.

I like the fact that the chapter integrated material from the ISA and REA. The reason I say this is that it gives the policy-maker two ways to consider a standard: one based purely on the health effects information from epidemiological and clinical studies, and one rooted in quantitative risk assessment. I have been involved recently in European Commission deliberations on these same air pollutants, and am struck by how much less computationally intensive the EC process is compared to that in the US. There is more reliance here on simply asking for the levels of SO2 and other compounds at which health effects have or have not been noted, and then going forward with regulation based on these data. So I was happy to see that Chapter 10 gives a decision-maker information directly from the ISA that might inform a decision, while also providing the more detailed and computationally intensive results of the REA.

2. I am comfortable with this discussion, Both the ISA information and these REA data suggest the current standard is inadequate, and this chapter makes that point directly without over-stating the science.

3. Again, I am comfortable with the characterization and the implications drawn. There is a vast amount of information in both the ISA and REA, and the authors have distilled this information and drawn what I find to be sound conclusions that will be clear to decision-makers.

4. I am comfortable with this range. The authors have presented their rationale in a way that can at least be fully understood. I would have preferred to see a bit more of a discussion of how the uncertainty in health effects below 50 ppb cause this to be the lower bound to be considered, but also realize it is a judgment call as to whether my claim about the uncertainty is correct. In any event, I believe the final standard is likely to fall somewhere within this range anyway, and the document presents a good case as to why this is a reasonable range to consider/

Comments from Dr Christian Seigneur

Comments on the 2nd draft REA for SO_2

Christian Seigneur
Cerea, Université Paris-Est

My comments pertain to the "*Characterization of the Air Quality and Exposure*". Overall, I find the air quality analysis to be technically sound. My main concern is the emphasis on industrial point sources and the small contribution of ship-related emissions in the area used for the exposure analysis (i.e., St Louis).

Charge question 1: Are the results of the air quality analyses technically sound?

Industrial point sources have historically been a major source of SO_2 and accordingly have been subjected to emission control regulations. Recently, SO_2 emissions from ships have become of concern and, in some areas, may be the major cause of significant SO_2 exposure. This issue is being addressed through the set up of Sulfur Emission Control Areas (SECAs), within which the sulfur content of the fuel will be constrained.

The 2nd draft REA correctly singles out ship-related emissions in the exposure analysis (e.g., port emissions in Table 8-5 on p. 178 and supporting text). However, the port emissions in St Louis are a small fraction of total SO_2 emissions in the area (about 3%). Such emissions may constitute a larger fraction of total SO_2 emissions in other areas (e.g., large sea ports such as Long Beach or Oakland in California). It would be useful if a discussion of this source of variability were included in the REA, perhaps in the uncertainty/variability section.

I found the model performance evaluation to be satisfactory, i.e., within the range of uncertainty expected from current atmospheric dispersion models. Among all the monitors where the model simulation results are compared to the available measurements, model performance appears to be poor only at monitor ID 290770040. The model reproduces the temporal evolution and magnitude of the measured SO_2 concentrations fairly well at the other eleven monitors. This satisfactory performance is not unexpected as point source emissions dominate the SO_2 emission inventory and the dispersion model used here, AERMOD, was designed for simulating atmospheric dispersion from point sources.

Charge question 4: Is the assessment of the uncertainty and variability adequate? To what extent has variability adequately been taken into account?

My main criticism of the uncertainty analysis (Section 8.11) is that it pertains mostly to an uncertainty analysis of the St Louis case study and fails to address variability among various urban areas. There is some discussion of the interurban variability of air exchange rates for example, but there is no discussion of the variability of emission sources among urban areas in the United States. Some discussion (at the minimum, a qualitative

discussion) of the variability of SO_2 exposure among various areas (see comments on ship-related emissions above) is warranted.