

## Review of the Risk and Exposure Assessment document for SO2

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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 less 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 SO<sub>2</sub> 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/