

09-13-17 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Sulfur Oxides Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

**Preliminary Comments from Members of the CASAC Sulfur Oxides Panel on  
EPA’s Policy Assessment for the Review of the  
Primary National Ambient Air Quality Standard for Sulfur Oxides  
(External Review Draft – August 2017)**

Received as of 09-13-17

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**Dr. John Balmes**

*Introduction and Background for the Policy Assessment (Chapter 1) - Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the SOx NAAQS and the decisions made in the last review, and a summary of the scope and approach for the current review.*

*1. Do I find the introductory and background material to be clearly communicated and appropriately characterized?*

Yes

*Current Air Quality (Chapter 2) - Chapter 2 provides information on emissions (section 2.1), air monitoring methods and network (section 2.2), and current air quality (section 2.3).*

*2. To what extent do I find this information to provide useful context for the review and to what extent is the information presented appropriately characterized and clearly communicated?*

I find the information presented to be useful in the context of evaluation of policy options and to be clearly and appropriately presented.

*Review of the Primary Standard (Chapter 3) - Chapter 3 summarizes the approaches for the last and current review of the primary standard for SOx (section 3.1), presents key evidence-based (section 3.2.1) and exposure/risk-based (section 3.2.2) considerations in the review, preliminary staff conclusions (section 3.2.3), and also identifies key areas of uncertainty and data gaps (section 3.3).*

*3. Consistent with the established NAAQS process, and the approach for the last and current reviews, the discussions of the health effects evidence and exposure/risk information have been organized around a set of policy-relevant questions for the review. Do I consider the document to provide the appropriate level of detail in addressing these policy-relevant questions?*

Yes

*4. The discussion of the health effects evidence (e.g., section 3.2.1) draws from the most recent information contained in the second draft ISA for SOx and information from the previous review described in previous Air Quality Criteria Documents.*

*a. Does the draft PA accurately reflect the key aspects of the currently available health effects evidence for SOx as characterized in the second draft ISA and the extent to which it differs from that available at the time of the last review?*

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1 As a member of the previous CASAC SO<sub>x</sub> review panel, I find that the draft PA accurately  
2 reflects the key aspects of the last review. I also think that it appropriately characterizes the key  
3 aspects of the current review.  
4

5 *b. Does the draft PA accurately reflect key uncertainties in the currently available health effects*  
6 *evidence for SO<sub>x</sub>, including with regard to concentrations eliciting effects in people with asthma,*  
7 *populations at risk, and the extent to which these uncertainties may differ from those existing at*  
8 *the time of the last review?*  
9

10 I think that the draft PA does a good job in characterizing key uncertainties that persist since the  
11 last review.  
12

13 *c. Do I find the presentation to be technically sound, clearly communicated, and appropriately*  
14 *balanced?*  
15

16 Yes  
17

18 *5. The discussion of the quantitative analysis of exposure and risk (section 3.2.2) draws from the*  
19 *analyses described in the draft Risk and Exposure Assessment (REA).*  
20

21 *a. Does this discussion accurately reflect the analyses contained in the draft REA, as well as*  
22 *associated key uncertainties and public health implications?*  
23

24 Yes  
25

26 *b. Do I find the presentation to be technically sound, clearly communicated and appropriately*  
27 *balanced?*  
28

29 Yes  
30

31 *6. This document has integrated health evidence from the second draft ISA and risk and exposure*  
32 *information from the draft REA as it relates to reaching preliminary staff conclusions about the*  
33 *adequacy of the current standard (section 3.2.3).*  
34

35 *a. Do I view this integration to be technically sound, clearly communicated, and appropriately*  
36 *characterized?*  
37

38 Yes  
39  
40  
41  
42

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1 *b. Does the document appropriately characterize the results of the draft REA, including their*  
2 *significance from a public health perspective?*

3  
4 Yes

5  
6 *7. What are my views regarding the staff's discussion of considerations related to the adequacy*  
7 *of the current standard? Does the discussion provide an appropriate and sufficient rationale to*  
8 *support preliminary staff conclusions?*

9  
10 I find that the staff discussion throughout the Policy Assessment clearly presents a careful review  
11 of the relevant information for a recommendation to the Administrator about the adequacy of the  
12 current standard. I agree that the information reviewed in the PA supports staff's preliminary  
13 recommendation to retain the current standard.

14  
15 *8. What are my views regarding the key uncertainties and areas for additional research and data*  
16 *collection that are identified in the draft PA (section 3.3)? Are there additional areas that should*  
17 *be highlighted?*

18  
19 My main concern is that the lack of controlled human exposure data for potentially susceptible  
20 populations, namely children with asthma and adults with severe asthma, are unlikely to be  
21 obtained in the future for ethical reasons. Another concern is that the epidemiological data  
22 needed to address the identified uncertainty about potential co-pollutant confounding of the  
23 association between short-term SO<sub>2</sub> exposures and asthma-related health care utilization will be  
24 hard to obtain in the US. As clearly identified in the draft ISA and REA, ambient levels of SO<sub>2</sub>  
25 are decreasing in the US such that it may be difficult to conduct studies of potential co-pollutant  
26 confounding in this country.

1 **Dr. Judith Chow**

2  
3 **Chapter 2: Current Air Quality**

4  
5 *2. To what extent does the Panel find this information to provide useful context for the review*  
6 *and to what extent is the information presented appropriately characterized and clearly*  
7 *communicated?*

8  
9 Chapter 2 gives a brief summary of SO<sub>2</sub> sources, ambient monitoring methods and networks,  
10 long-term SO<sub>2</sub> trends and variability, and the relationship between 5-minute and 1-hour SO<sub>2</sub>  
11 concentrations. Although most of this chapter is consistent with the Second Draft ISA (U.S.  
12 EPA, December 2016), it has little connection with the data periods and modeling domains  
13 presented in the REA External Review Draft (U.S. EPA, August 2017). Some clarification is  
14 needed to demonstrate consistency among the ISA, REA, and PA.

15  
16 The effectiveness of several control measures implemented over the past 30 years is made clear  
17 by the emission trends from 1990 to 2016 (Figure 2-2, Page 2-3). However, the analysis based on  
18 the U.S. EPA 2014 National Emissions Inventory (NEI) is inconsistent with the 2011 NEI used  
19 for the REA External Review Draft (U.S. EPA, August 2017). The differences in emissions and  
20 distribution between 2014 and 2011 NEI emissions for the three selected study areas should be  
21 documented.

22  
23 The data period in the Second Draft ISA (U.S. EPA, December 2016) and PA External Review  
24 Draft (U.S. EPA, August 2017) show data availability until 2015. However, SO<sub>2</sub> data from 2011-  
25 2013 was used in the REA External Review Draft (U.S. EPA, August 2017). The uncertainties of  
26 using 2011 NEI emissions and 2011-2013 SO<sub>2</sub> measurements for air quality exposure modeling  
27 need to be clarified.

28  
29 Figure 2-21 (Page 2-53) of the Second Draft ISA (U.S. EPA, December 2016) shows 1-hour  
30 daily maximum concentrations for the 1980-2015 period from 163 sites, while temporal trends in  
31 SO<sub>2</sub> concentrations for the same period in Figure 2-4 (Page 2-5) only include 45 sites. The  
32 rationale for selection of less than 30% of the sites to illustrate the 35-year trend should be given.  
33 Including a larger number of sites in the analysis should be more representative of the overall  
34 declines in SO<sub>2</sub> concentrations, probably at different rates of reduction.

35  
36 Section 2.3.2 updates geographical variations in SO<sub>2</sub> concentrations, highlighting the six areas in  
37 the Second Draft ISA (U.S. EPA, December 2016). Similar analysis should be completed for the  
38 three selected study areas using AERMOD and exposure modeling in the REA External Review  
39 Draft (U.S. EPA, August 2017) with regard to seasonal patterns/variations and variability in SO<sub>2</sub>  
40 concentrations across local and regional scales.

1 Analysis concerning the relationships between 5-minute and 1-hour SO<sub>2</sub> measurements was  
2 carried out for 2013-2015 data. Similar analysis should be conducted for the 2011-2013 data  
3 used for the three study areas in the REA External Review Draft (U.S. EPA, August 2017). The  
4 statistics in Figure 2-8 (Page 2-11) show that for areas with design values at or below the current  
5 standard of 75 ppb, 99.9% of daily maximum 5-minute concentrations are at or below ~150 ppb.  
6 It would be helpful to verify whether the same statistics apply to the three study areas in the  
7 REA.

### 10 **Chapter 3: Review of the Primary Standard**

11  
12 *8. What are the views of the Panel regarding the key uncertainties and areas for additional*  
13 *research and data collection that are identified in the draft PA (section 3.3)? Are there*  
14 *additional areas that should be highlighted?*

15  
16 With respect to ambient SO<sub>2</sub> monitoring data, it is encouraging that the number of air quality  
17 sites reporting twelve consecutive 5-minute concentrations for each hour has increased since  
18 2010. Unfortunately, as of 2016, only 40% of the sites report all twelve 5-minute SO<sub>2</sub>  
19 measurements for each hour. EPA should require states to report each 5-minute SO<sub>2</sub>  
20 concentration to evaluate the duration of plume touchdown and downwind mixing for the next  
21 round of SO<sub>2</sub> standard review. The short-duration measurements will also facilitate a better  
22 understanding of exposure durations and patterns with regard to relevant health benchmarks.

23  
24 Compared to the last SO<sub>2</sub> review in 2010, improvements have been made with respect to air  
25 quality model input (e.g., increased number of twelve 5-minute measurements for each hour);  
26 sensitivity analysis (e.g., estimates of continuous 5-minute SO<sub>2</sub> concentrations and adjustment of  
27 air quality level to just meet 75 ppb standard); simulation periods (i.e., three years, to be  
28 consistent with current standard of averaging time); number and types of study areas  
29 (representing different SO<sub>2</sub> emission levels and exposure patterns exhibiting different  
30 magnitudes of exposure); exposure modeling input (e.g. updated consolidated human activity  
31 database [CHAD] and updated NHANES database for body mass distribution); and algorithms  
32 for exposure modeling (e.g., updated age- and gender-specific resting metabolic rate and  
33 ventilation rate).

34  
35 However, many of the uncertainties associated with quantitative estimates of exposure and risk  
36 (e.g., lack of finer spatial-scale gradient, limited epidemiological and toxicological studies, and  
37 consideration of co-pollutants) are similar to those of the 2010 review. To improve the spatial-  
38 scale, EPA might consider the use of less costly and more portable SO<sub>2</sub> instrumentation (Dye et  
39 al., 2014; Snyder et al., 2013; Wang and Brauer, 2014) which are of growing interest for  
40 community involvement and exposure assessment.

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1 As current reviews are focused on single criteria pollutants to protect public health,  
2 multipollutant air quality management that considers the confounding factors or synergistic  
3 effects of co-pollutants should be considered in the future (e.g., Scheffe et al., 2009; Hidy and  
4 Pennell, 2010).

## 6 **References**

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27 Research Triangle Park, North Carolina 27711.

28 U.S. EPA (2014) National Emissions Inventory Report. U.S. Environmental Protection Agency,  
29 Research Triangle Park, North Carolina 27711.

30 <https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data>

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32 Research Triangle Park, North Carolina 27711.

33 <https://www.epa.gov/air-emissions-inventories/2011-national-emissions-inventory-nei-data>

**Dr. Aaron Cohen**

1  
2  
3 *Charge Question 4 - The discussion of the health effects evidence (e.g., section 3.2.1) draws from*  
4 *the most recent information contained in the second draft ISA for SOx and information from the*  
5 *previous review described in previous Air Quality Criteria Documents.*

6  
7 a. *Does the draft PA accurately reflect the key aspects of the currently available health*  
8 *effects evidence for SOx as characterized in the second draft ISA and the extent to which*  
9 *it differs from that available at the time of the last review?*

10  
11 Overall, yes it does, but see specific comments re. respiratory effects of long-term  
12 exposure in draft PA.

13  
14 b. *Does the draft PA accurately reflect key uncertainties in the currently available health*  
15 *effects evidence for SOx, including with regard to concentrations eliciting effects in*  
16 *people with asthma, populations at risk, and the extent to which these uncertainties may*  
17 *differ from those existing at the time of the last review?*

18  
19 Yes it does. Nice summary.

20  
21 c. *Does the Panel find the presentation to be technically sound, clearly communicated, and*  
22 *appropriately balanced?*

23  
24 I do overall, but made several drafting suggestions in the draft PA.

25  
26 Specific Comments

27  
28 p. 3-15, lines 16-18 - Was the determination re. long-term exposure and respiratory effects not a  
29 change from the previous ISA? If so, then better to say in lines 11-12 that "the current evidence  
30 largely supports..."

31  
32 p. 3-18, lines 21-24 – See comment above.

33  
34 p. 3-19, lines 26-27 - Suggest: "The adverse health effects associated with exposure to SO2 may  
35 be particularly severe among specific groups in the general population."

36  
37 p. 3-20, line 7 – Suggest changing “while at elevated ventilation” to "... when pulmonary  
38 ventilation is increased as with exercise."

39  
40 p. 3-20, lines 11-15 - Suggest: "The second draft RFA, using a more systematic approach to the  
41 evaluation of the current evidence, concludes that children and older adults are potentially more

- 1 susceptible to the adverse effects of exposure, strengthening the conclusion of the previous  
2 review."  
3  
4 p. 3-21, line 23 – Suggest changing “have been found” to “had been observed to increase...”  
5  
6 p. 3-22, line 24 – Suggest changing “during elevated ventilation” to “during exercise-induced (?)  
7 elevated ventilation...”  
8  
9 p. 3-28, lines 19-23 – Suggest changing to “The evidence for acute respiratory effects in at-risk  
10 populations exposed by mouthpiece ventilation for 5-10 minutes at concentrations below 200  
11 ppb is very limited because the studies are small. This limitation notwithstanding, these studies  
12 indicate...”  
13  
14 p. 3-31, lines 12-14 – Suggest changing to “Estimates of the public health impact of exposure to  
15 SO<sub>2</sub> in ambient air are based on those effects that have been shown to have a causal relationship  
16 with such exposure.”

1 **Dr. Alison Cullen**

2  
3 **Chapter 3 Review of the Primary Standard**

4  
5 *Charge Question 5 - Quantitative Analysis of Exposure and Risk*

6  
7 *The discussion of the quantitative analysis of exposure and risk (section 3.2.2) draws from the*  
8 *analyses described in the draft Risk and Exposure Assessment (REA)*

9  
10 *a. Does this discussion accurately reflect the analyses contained in the draft REA, as well as*  
11 *associated key uncertainties and public health implications?*

12  
13 The discussion accurately reflects the analyses contained in the draft REA, and lays out the  
14 associated key uncertainties and public health implications. The discussion of minimizing the  
15 number of microenvironments for efficiency should be elevated beyond a footnote on page 3-38  
16 and into the main text, this is clear and important.

17  
18 A question raised in earlier draft documents, why modeling at levels below “just meeting the  
19 current standard” was not pursued, still stands in this section. If this is now included in another  
20 part of the PA or REA, then a cross reference here would be appreciated as the simulation of the  
21 at-risk population exposures and risk relies on the approach to setting this levels in the  
22 simulation. If there is not new content in another section then addition here makes sense.

23  
24 On page 3-37 in lines 20-23 the approach to simulating individuals is summarized – selecting  
25 values for demographic variables, status and physical attributes and ventilation rate. Additional  
26 information appears in section 3.2.2.2. Although REA Table 6-2 itemizes to some extent  
27 potential co-variability and joint variability between categories of inputs which was accounted  
28 for explicitly or stochastically in the analysis, it would be very helpful to include detailed  
29 information about specifically which interrelationships are accounted for in this simulation. This  
30 level of detail is missing from the Table 6-2 which is quite helpful and clear otherwise, i.e., is  
31 correlation and/or interrelationship between socioeconomic status and presence of air  
32 conditioner, or interrelationship between study area and socioeconomic structure including age  
33 distribution included. If this content appears elsewhere then a cross reference to that location  
34 from Table 6-2, and also in the PA at this location, would clarify.

35  
36 The lack of information about severe asthmatics and also children under age 12 (with asthma in  
37 particular) is well documented and acknowledged as a source of uncertainty about the analysis as  
38 these would represent the population of greatest risk. There are 24 million asthmatics in the US  
39 and 6 million of these are children. In some areas a modeled estimate of 25% (or more in some  
40 years) of children with asthma will experience at least one day with 5 minute exposure at or  
41 above 100 ppb while breathing at elevated ventilation rates, and 1% of asthmatic children are

1 estimated to experience at least one day per year of SO<sub>2</sub> related increase of sRaw of 100% or  
2 more (doubling), which again raises questions about modeling at the level of “just meeting” the  
3 standard, as this is very close to the 100 ppb level. Further there is a question of whether  
4 statements such as on page 3-57 line 16-17, that there is continued “support for a standard as  
5 protective as the current one” and lines 35-36 that this standard is “consistent with the level of  
6 protection specified when the (current) standard was set” seem to fall short of declarations of an  
7 adequate margin of safety.

8  
9 *b. Does the Panel find the presentation to be technically sound, clearly communicated and*  
10 *appropriately balanced?*

11  
12 The presentation is overall technically sound, clearly communicated and appropriately balanced,  
13 although a few additional points and questions remain as outlined below.

14  
15 Page 3-36 line 10-12 Please include the information about which 2 of the 3 study areas have  
16 continuous 5 minute monitoring data available, rather than just alluding to the 2 out of 3 in the  
17 text of this section, especially since the continuous data are an important and integral link to the  
18 estimation of 5 minute exposures.

19  
20 Page 3-36 lines 14-15 (and throughout) Be clear about what the variance ranges refer to in all of  
21 these portions when ranges of percentage of the population is mentioned, e.g., across census  
22 blocks within a study area, across the areas themselves, or other.

23  
24 Page 3-36 lines 22-24 This portion is confusing, either just refer to the REA (with sections,  
25 pages and line numbers) regarding the adjustment approach or repeat the relevant information  
26 about the adjustment approach in brief here.

27  
28  
29 *Charge Question 6 - Integrated Health Evidence, and Risk and Exposure Information*

30  
31 *This document has integrated health evidence from the second draft ISA and risk and exposure*  
32 *information from the draft REA as it related to reaching preliminary staff conclusions about the*  
33 *adequacy of the current standard (section 3.2.3)*

34  
35 *a. Does the Panel view this integration to be technically sound, clearly communicated and*  
36 *appropriately characterized?*

37  
38 The integration of health evidence with risk and exposure information appears to be technically  
39 sound, clearly communicated.

40  
41 As referred above, in some areas an estimated 25% (or more in some years) of children with  
42 asthma will experience at least one day with 5 minute exposure at or above 100 ppb while

1 breathing at elevated ventilation rates, and 1% of asthmatic children are estimated to experience  
2 at least one day per year of SO<sub>2</sub> related increase of sRaw of 100% or more (doubling), which  
3 again raises questions about modeling at the level of “just meeting” the standard, as this is very  
4 close to the 100 ppb. Further questions of whether statements such as on page 3-57 line 16-17,  
5 that there is continued “support for a standard as protective as the current one” and lines 35-36  
6 “consistent with the level of protection specified when the (current) standard was set” seem to  
7 fall short of declarations of an adequate margin of safety. This reasoning seems to be that this  
8 level was determined adequate in past analysis and no new information relevant to SO<sub>2</sub> has been  
9 identified in the literature thus there is no change. One question is whether the NAAQS process  
10 for any other air contaminant (PM, O<sub>3</sub>, etc) has led to a different interpretation of evidence or  
11 different approaches subsequent to the last SO<sub>2</sub> standard’s determination of adequacy?  
12

13 *b. Does the document appropriately characterize the results of the draft REA including their*  
14 *significance from a public health perspective?*  
15

16 The public health impact of SO<sub>2</sub> is well described, the magnitude of the population at potential  
17 risk appropriately characterized. As mentioned just above it is important to consider whether  
18 other NAAQS processes for other air contaminants have added anything to the adequacy  
19 determination for SO<sub>2</sub>.  
20

21 *Charge Question 8 - Key Uncertainties and Areas for Additional Research and Data Collection*  
22

23 *What are the views of the Panel regarding the key uncertainties and areas for additional*  
24 *research and data collection that are identified in the draft PA (section 3.3)? Are there*  
25 *additional areas that should be highlighted?*  
26

27 The key uncertainties identified in section 3.3 are important and clear; however there is very  
28 little quantitative information about the relative magnitude of these categories of uncertainty in  
29 this section. REA section 6 contains some additional information which could be cross  
30 referenced here.  
31

32 The lack of data particularly about lower concentrations is an acknowledged concern. The  
33 exposure response data such as plotted in Figure 4-1 of the draft REA, along with observations  
34 of considerable variability in the range of the lowest concentrations studied (200-300 ppb), lends  
35 extra weight to this point.  
36

37 “Responders” are mentioned at the top of page 3-59, as a subgroup of asthmatics however in this  
38 current PA there is no additional mention of them (the reader is referenced to the second draft  
39 ISA). There should be a very brief definition here (less than a sentence) stating what about it is  
40 about these responders that puts them in this category of more susceptibility.  
41

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1 The inclusion of less than a third of the CHAD data in developing human activity patterns was  
2 mentioned in the REA, this was a result of a lack of breakdown information about time spent  
3 indoors and outdoors. The idea that perhaps such a breakdown ratio could be developed based on  
4 the CHAD data for which the indoor/outdoor information is available and then applied to the  
5 other two thirds of the dataset merits consideration given the amount of data that is unusable on  
6 this basis.

**Dr. Steven Hanna**

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Note that my expertise is primarily in atmospheric transport and dispersion modeling, analysis of observed concentrations, and analyses of uncertainty and variability. My comments focus on those areas.

*Charge Question 5. The discussion of the quantitative analysis of exposure and risk (section 3.2.2) draws from the analyses described in the draft Risk and Exposure Assessment (REA).*

*a. Does this discussion accurately reflect the analyses contained in the draft REA, as well as associated key uncertainties and public health implications?*

There are additional uncertainties associated with the non-representativeness of the observing sites providing the input meteorological data and the 5-minute average SO<sub>2</sub> monitoring data. These sites are as much as 10 to 20 km distant from the point source location and the location of the DV. For example, uncertainties in wind direction of 20 or 30 degrees or more are common and could cause a modeled plume to hit or miss a large population center.

*Charge Question 8. What are the views of the Panel regarding the key uncertainties and areas for additional research and data collection that are identified in the draft PA (section 3.3)? Are there additional areas that should be highlighted?*

See above. Also, the spatial variability of met and 5-minute concentration data sets can be assessed by analyzing data from monitors that are located close together in the same domain. Furthermore, I note that we know that the spatial and temporal variability is mostly determined by mesoscale fluctuations in wind and turbulence. Variances and integral space and time scales are available in the literature. The dispersion model SCIPUFF (in SCICHEM) parameterizes these time and space scales.

In some of my uncertainty analyses, I run the dispersion model using several optional wind inputs (e.g., nearest NWS site, nearest tower or other network site, WRF, etc.). This ensemble of models produces an “uncertainty cone” (such as seen in hurricane track forecast models).

**Dr. Daniel Jacob**

**Chapter 2**

**Response to charge question:** the material in this chapter is useful to the PA and clearly communicated, I just have a few comments:

Page 2-1, line 18. If you're going to mention SO<sub>3</sub> then you would need to mention a menagerie of minor sulfur oxides including H<sub>2</sub>SO<sub>4</sub>(g), MSA, DMSO...I think it would be better to just say that SO<sub>2</sub> is the main gas-phase sulfur oxide in the atmosphere and leave it at that. Somewhere in this chapter, give the sink and lifetime of SO<sub>2</sub>?

Page 2-1, line 28. Should the contributions of metal smelters and oil refineries be identified as additional sources of SO<sub>x</sub>?

Page 2-5, Figures 2-4 and 2-5. Need to tell us what the purple envelope represents. This is of some importance because the envelope extends above the NAAQS in Figure 2-4 but not in Figure 2-5.

Page 2-8, Figure 2-7. In this figure you need to comment on the exceedances in Hawaii as due to volcanic source. Else reader wonders. What about the exceedances away from the industrial Midwest, such as in the West? Are they due to nearby power plants or to other sources such as smelters?

Page 2-9, line 20. This suggests that there is diurnal variability in SO<sub>2</sub> emissions but there really is not.

Page 2-11, line 15. Do you mean "400 or even 100 ppb"?

1 **Dr. Elizabeth A. (Lianne) Sheppard**

2  
3 General comments

4  
5 Overall I found this document to be well organized and very readable. It captures the essential  
6 concepts for guiding policy. I note that the document does not provide an explicit discussion of  
7 the four basic elements of a standard in its discussion of the preliminary staff conclusions to  
8 retain the current standard (Section 3.2.3). Is this an omission, or are we comfortable with the  
9 discussion of the form, indicator, averaging time and level that is covered in earlier parts of the  
10 document?

11  
12 *CQ 5: The discussion of the quantitative analysis of exposure and risk (section 3.2.2) draws from*  
13 *the analyses described in the draft Risk and Exposure Assessment (REA).*

14  
15 *a. Does this discussion accurately reflect the analyses contained in the draft REA, as well as*  
16 *associated key uncertainties and public health implications?*

17  
18 My first review suggests the discussion is accurate. The comment about the significance of the  
19 overlap between locations with high exposure and locations with higher population density is an  
20 important point made in the public health implications discussion. I found myself asking how  
21 many other locations in the US are like the Fall River location. The figures in Appendix F  
22 suggest visually that this overlap isn't uncommon. I wonder whether it should be quantified more  
23 clearly in Section 3.2.2.

24  
25 *b. Does the Panel find the presentation to be technically sound, clearly communicated and*  
26 *appropriately balanced?*

27  
28 Yes

29  
30 *CQ 7: What are the views of the Panel regarding the staff's discussion of considerations related*  
31 *to the adequacy of the current standard? Does the discussion provide an appropriate and*  
32 *sufficient rationale to support preliminary staff conclusions?*

33  
34 I think the discussion is appropriate and sufficient rationale has been provided to support the  
35 preliminary staff conclusions. As I mention above, we should consider whether the discussion in  
36 Section 3.2.3 should revisit the four basic elements of the standard. Even a sentence that states  
37 that the staff do not recommend any changes to any of these might be useful to add.

38  
39 *Minor comments:*

40  
41 P 3-3 footnote: I think the discussion is of the term "elevated exertion"

1 **Dr. Frank E. Speizer**

2  
3  
4 Section 3.11, pages 3.2-3.11 does an excellent job of summarizing the 2009 REA and provides  
5 the logic for the Indicator, Averaging time, Form, and Level from the previous round for the  
6 2010 SO2 NAAQS.

7  
8 Approach for the current round is adequately presented and is summarized on page 3.19  
9 concluding that "... rather than altering our conclusions from the previous review, the current  
10 evidence provides continued support for our previous conclusions... regarding the health effects  
11 associated with exposure to SO2 and most particularly respiratory effects following short-term  
12 SO2 exposure, particularly in individuals with asthma." I concur, however; there is an Issue on  
13 susceptibility: from text...page 3.21 This study uses the available individual subject data from  
14 five studies involving exposure of individuals with asthma to multiple concentrations of SO2 for  
15 5 to 10 minutes while at elevated ventilation to examine the differences in lung function response  
16 (Johns et al., 2010). As noted in the second draft ISA, "these data demonstrate a bimodal  
17 distribution of airway responsiveness to SO2 in individuals with asthma, with one subpopulation  
18 that is insensitive to the bronchoconstrictive effects of SO2 even at concentrations as high as 1.0  
19 ppm, and another subpopulation that has an increased risk for bronchoconstriction at low  
20 concentrations of SO2" (second draft ISA, p. 5-17). To date, the characteristics that may define  
21 the subpopulation of responders have not been identified. **The current evidence for factors  
22 other than those discussed above (asthma status and lifestage) is inadequate to determine  
23 whether they might contribute to an increased risk of SO2-related effects (second draft  
24 ISA, section 6.6).**  
25

26 This last sentence seems to beg the question that there are susceptibility factors that leave some  
27 individuals at risk, and probably explains why in population studies at lower levels of exposure  
28 there may not be population mean risks that reach significant levels in a classical sense, and are  
29 thus being interpreted as measures of uncertainty. However, under margin of safety it would  
30 seem that there clearly are individuals at risk.

31  
32 Page 3.27, Uncertainties. Second para. "s. Such uncertainties include those associated with  
33 severity and prevalence of responses to very short (5- to 10-minute) SO2 exposures below 200  
34 ppb and responses of some population groups not included in the controlled exposure studies  
35 (e.g., those with more severe asthma and children)."

36  
37 Rather than characterizing this as an uncertainty, I believe it really is a lack of data. It certainly is  
38 NOT that the effect might be less likely to be significant if children had been studied.

39  
40 Similarly, on page 3.28, para 2 starting line 7 suggesting that the effects in children below age 12  
41 is a phenomena of "uncertainty" seems a misguided concept. Although the paragraph brings out

1 why there are no data and suggest that effects might be greater the issue is not “uncertainty” (as  
2 used in this document) but really “not quantifiable” as formal studies in children (and more  
3 severe asthmatics) simply have not been done and in fact might be unethical to do. I think this is  
4 captured in the summary statement in 5 on page 31, but might be made stronger than linking it as  
5 part of an uncertainty statement.

6  
7 The term “uncertainty” is more appropriately applied subsequently in consideration of actual  
8 ambient and mixed exposures, and for the long term and other mentioned health outcomes.

### 9 10 Section 3.2.2 Exposure/Risk based Considerations

11  
12 Page 2.11, Figure 2.8 and Appendix C provide data for the updating of 5 minute averages for  
13 2013-2015 period. These data suggest that: For DV < 75 (current standard) there are monitors in  
14 the dataset with as many as 70 days with a 5-min concentration >100 ppb, as many as 22 days  
15 with a 5-min concentration >200 ppb, as many as 8 days with a 5-min concentration >300 ppb,  
16 and as many as 5 days with a 5-min concentration >400 ppb This translates in text on page 3.41  
17 to 20-25% of children with asthmas over a 3 year period experiencing 1 or more days per year  
18 with 5 minute exposure above 100ppb while exercising and 0.7% experiencing exposures at or  
19 above 200ppb., . **These data were not available in the previous round of consideration and**  
20 **thus raises the issue of whether the 1 hour at 75ppb in really protective with an adequate**  
21 **margin of safety, if particularly we want to protect the most vulnerable of asthmatics to**  
22 **level of 200ppb (particularly since the MOST vulnerable—younger severe asthmatics—are**  
23 **not even in these calculations. FOR DISCUSSION**

24  
25 In spite of above, the argument made in text section 3.2 provides reasonable support for maintain  
26 the current standard. However, it clearly indicates that 1-2% of mild to moderate asthmatics will  
27 suffer significant adverse effects/year as result of allowable exposures. Of concern is the fact that  
28 it is likely that younger and more severe asthmatics will suffer if not more frequently, more  
29 severely, and thus raises the possibility of required hospitalization for most particularly those  
30 living in urban areas. This could result in an estimated additional 12,000-24,000 hospitalizations.  
31 Is this acceptable for a standard with an **adequate margin of safety?**

32  
33 Page 3.57, sentence beginning line 24. I believe it would be worth adding to and re-wording this  
34 sentence to reinforce the issue regarding more severe asthmatics. Suggest: : “ In so doing, we  
35 recognize the limitations in the evidence available for lower exposure concentrations (e.g., 100  
36 ppb), as was the case in the last review, and the unavailable potential response data among more  
37 severe asthmatics, as well as the uncertainties regarding mixed exposures at these lower levels.

38  
39 Page 3-58, line 33: This bullet needs to be modified as to become a discussion **NOT of whether**  
40 more severely affected populations are a risk at lower level but quantitating the % and magnitude  
41 of that risk.

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- 1 Page 3-59, line 23; I take offense with the word “gleaned” which suggest that epidemiology does
- 2 not produce scientific finding but only chance observations. Suggest change to “learned”
- 3
- 4 Page 3-59, sentences beginning lines 33 and 38: Suggest change to full sentences.

**Dr. James Ultman**

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*Question 5. The discussion of the quantitative analysis of exposure and risk (section 3.2.2) draws from the analyses described in the draft Risk and Exposure Assessment (REA).*

*a. Does this discussion accurately reflect the analyses contained in the draft REA, as well as associated key uncertainties and public health implications?*

Yes, section 3.2.2 does meet these goals. However, the material in this section is quite repetitive. This occurs because the section is organized around a series of questions that require overlapping discussions. Nevertheless, an attempt should be made to streamline the text.

*b. Does the Panel find the presentation to be technically sound, clearly communicated and appropriately balanced?*

Yes, section 3.2.2 is technically sound and appropriately balanced. As I suggest above, the clarity of the presentation suffers somewhat from redundancy.

Additional Comments

pg 2-10, footnote 10. This is a general definition of design value. A definition specific to the way design value was computed in this PA is needed.

pg 3-20, line 18. I think that lung development should be named as a characteristic of children that may make them more at risk than adults.

pg 3-39, line 10. Table 4-9 should read table 4-6.

pg 3-57, line 13 Correct spelling of approximately.

**Dr. Ronald Wyzga**

Overall Comments

The document is clearly written and well communicates the justification for its recommendations of the standard. I have two general comments. 1.) SO<sub>2</sub> emissions have declined significantly over the past several years. The REA used to support the recommendations here is based upon 2011–2013 data. Figure 2,2 in this document gives data to 2016, and we note the decline between 2013 and 2016. (Figure 2-4 supports this with concentration data through 2015.) The continuing decline in SO<sub>2</sub> emissions and its implications should be more clearly discussed in this document; specifically, it should note that the exposures/risks estimated in the REA likely would decrease given more recent emissions data. Hence these recent reductions give even greater support to the rationale expressed in this document. 2.) Given then role of the past (2000) ATS policy statement in the Administrator’s decision in the past, and the discussion of the new ATS policy statement (2017) in this document, it would be useful to articulate the differences between these two statements in an Appendix. The document alludes to the 2017 ATS statement and notes that the discussion is not contradicted by the 2017 statement.

*Charge Question: What are the views of the Panel regarding the key uncertainties and areas for additional research and data collection that are identified in the draft PA (section 3.3)? Are there additional areas that should be highlighted?*

By and large the document clearly identifies the key uncertainties. It could be helpful if there could be more discussion about potential future research. For example, the document clearly states the need for greater understanding of the response of childhood and severe asthmatics to SO<sub>2</sub> exposure. Human clinical studies have been used to generate the information used to set the current standard, but this approach is unlikely to be possible for either of the above two groups. Some discussion about potential approaches to generate the needed information would be helpful. They could, for example, focus on the need for better estimates of SO<sub>2</sub> uptake in these groups and information on the underlying mechanism between SO<sub>2</sub> exposure and response. Innovative epidemiological studies could also help here.

The one area that is not mentioned that could be of value would be the collection of personal SO<sub>2</sub> exposure data; this could also involve the development of instruments that passively measure exposures for short periods of time.

Specific Comments:

Pp, 2-5 and 2-6: I am confused by the differences between Figures 2-4 and 2.5. Could there be more discussion of why they differ?

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- 1 p. 3-35, ll. 33-35: It could be noted in a footnote that the major source of SO<sub>2</sub> for this population  
2 had since closed.  
3
- 4 pp. 3-42, 3-43: The above comment could also be made for the Fall River estimates.  
5
- 6 p. 3-54, ll. 18-19: It could be pointed out that SO<sub>2</sub> emissions have declined since the 2011-13  
7 period in the REA analyses.  
8
- 9 p. 3-56, ll. 12-16: Reductions since 2013 would lead to an even greater estimate of the number of  
10 children protected.  
11
- 12 Appendix F; Is there a more recent series of figures available?  
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14  
15  
16