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April XX, 2009

EPA-CASAC-09-00X

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

Subject: Clean Air Scientific Advisory Committee's (CASAC) Review of *EPA's Risk and Exposure Assessment (REA) to Support the Review of the SO₂ Primary National Ambient Air Quality Standards: Second Draft*

Dear Administrator Jackson:

The CASAC Sulfur Oxides Primary National Ambient Air Quality Standards (NAAQS) Review Panel (see Enclosure A for Panel Roster) is providing review comments on the Environmental Protection Agency's (EPA) second draft *EPA's Risk and Exposure Assessment (REA) to Support the Review of the SO₂ Primary National Ambient Air Quality Standards: Second Draft*.

This letter provides CASAC's overall comments, highlighting the most important issues to be addressed in revising the second draft REA. Responses to the specific charge questions (Enclosure B) and comments from individual Panel members (Enclosure C) follow.

The second draft REA was greatly improved and CASAC found that its comments on the first draft had largely been addressed. The REA builds successfully on the Integrated Science Assessment (ISA) and its methodology is generally well described. CASAC supports the approach that was taken and concludes that the REA offers the analyses and findings needed for determining the four elements of the NAAQS for SO₂. Chapter 10, which is specifically relevant to that purpose, sets out a framework of evidence for decision making, while simultaneously identifying key uncertainties. CASAC is in agreement with having a short-term standard and finds that the REA supports a 1-hr standard as protective of public health. It is also in agreement with the proposed range for a 1-hr standard of 50-150 ppb; it recommends further analyses to better characterize the implications of selecting the 98th or 99th percentile for the form.

1 The principal comments to be addressed as the document is revised primarily relate
2 to its organization and the need for greater clarity in communicating key aspects of the
3 methods and findings, particularly those related to uncertainty and variability. We
4 strongly urge the following:

- 5
6 • Every chapter in this or any REA (as well as in the ISAs) should end with a
7 summary section that covers findings relevant to the considerations around the
8 NAAQS, presented in Chapter 10 in this REA. The summaries should
9 specifically consider:

10 What scientific evidence and/ scientific insights have been developed
11 since the last review that either support or call into question the current
12 public-health-based and/or current public-welfare-based NAAQS, or
13 indicate that alternative levels, indicators, statistical forms, or averaging
14 times of the standards are needed to public health with an adequate margin
15 of safety and to protect public welfare.

- 16
17 • CASAC found the discussions of uncertainty in the various chapters to be lacking
18 in clarity, with incomplete descriptions of methods and findings. We recommend
19 rewriting with more complete description of methods and highlighting of key
20 findings, perhaps with bullets, rather than in lengthy text. Sensitivity analyses
21 need to be distinguished from those addressing uncertainty.
- 22 • The health endpoints in the clinical studies, increase in airways resistance (sRaw)
23 and decrement in forced expiratory volume in one second (FEV₁), need to be
24 better framed as indicative of an adverse consequence of SO₂ exposure. There
25 needs to be expanded discussion of why these are informative measures and of
26 their clinical implications.
- 27 • Chapter 3.0 needs extensive revision. It reads poorly and does not satisfactorily
28 define nor address the key concepts of susceptibility and vulnerability. The EPA
29 should carefully compare the content of this chapter to that of similar chapters in
30 ISAs and REAs.
- 31 • To the extent possible, the REA should better address the representativeness of
32 the locations with SO₂ monitors considered in the REA as well as of Greene and
33 St. Louis Counties, where the risk analysis was carried out.

34 This revision was submitted without responses to the comments in the CASAC letter
35 on the first draft REA and also without any indication of changes since the prior draft.
36 CASAC reiterates its expectation that all revised drafts will be accompanied by such
37 materials, both to enhance the efficiency and targeting of its review and to provide a
38 transparent record of the basis for changes.

39
40 With reviews in progress for the gaseous criteria pollutants and well as for particulate
41 matter (PM), CASAC notes the inherent oversimplification of handling these components

CASAC Draft Report (04-17-09) to Assist Meeting Deliberations -- Do not Cite or Quote -- This draft is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered CASAC and does not represent EPA policy.

1 of the ambient air pollution mixture on an individual basis. Consideration needs to be
2 given to how the existence of the criteria pollutants in mixtures can be better
3 acknowledged and to strategies for moving towards regulatory strategies that are built on
4 understanding of health risks of ambient pollution mixtures.
5

6 In closing, ...
7

8 Sincerely,
9

10 Dr. Jonathan M. Samet, Chair
11 Clean Air Scientific Advisory Committee
12
13

14
15 Enclosures

CASAC Draft Report (04-17-09) to Assist Meeting Deliberations -- Do not Cite or Quote -- This draft is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered CASAC and does not represent EPA policy.

Enclosure A

ROSTER

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

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Enclosure B
Responses to Agency Charge questions

Discussion and response to Agency charge questions relating to characterization of air quality (chapters 2, 5, 6, and 7)1:

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

There were substantial improvements in this work since the last version. There has been a good effort to incorporate more information about sites but concern remains that siting features are not well understood and may be affecting the inference. SO₂ is highly influenced by local sources. The air quality analysis assumes the universe of monitoring data represents a reasonable sample for analysis, yet we don't know if the available monitors are representative of a defined underlying population. Furthermore, there is an assumption that site-years are exchangeable. There should be a description of the monitoring network design in Chapter 2 and further analysis of the network features in Chapter 7.

A second concern is that only one 5-minute exceedance per day was counted. While from some policy perspectives this choice is reasonable, this approach needs to be described and justified early in the document. Consider new wording "number of days with at least one 5-minute concentration above potential health effect benchmark levels" instead of "numbers of daily maximum 5-minute concentration exceedances" or similar language.

2. *In order to simulate just meeting potential alternative 1-hour daily maximum standards, we have adjusted SO₂ air quality levels using the same approach that was used in the first draft to simulate just meeting the current standards. What are the Panel's views on this approach? To what extent does this approach characterize the public health implications of the current standards? Does the Panel have technical concerns with this approach?*

The Panel recognizes that there are proportionally increasing the concentrations up to simulate just meeting the standard does not fully account for what would happen if the reasons why current SO₂ levels are under the current NAAQS, but we agree with using a simple, transparent approach that does not involve making a number of additional assumptions.

3. *In this second draft document, the locations selected for detailed analyses were expanded from twenty to forty counties, using ambient SO₂ monitoring data for years 2001-2006. What are the views of the Panel regarding the appropriateness of these locations and time period of analysis? To what extent is the rationale for selection of these locations and time periods clear and sufficient to justify their use in detailed air quality and exposure analyses?*

Choosing urban areas with multiple monitors for inclusion in the analysis is certainly reasonable. Including an additional metric targeting those urban areas with

1 levels relatively close to the current standard is also reasonable. It would be interesting to
 2 know how many of these counties are classified “c” with respect to their coefficient of
 3 variation (potential for relatively high peak to mean ratios), and alternately, how many
 4 were not included. This information is in the Appendix and could easily be extracted in a
 5 few sentences

- 6
 7 4. *What are the views of the Panel regarding the adequacy of the assessment of*
 8 *uncertainty and variability? To what extent have sources of uncertainty been*
 9 *identified and the implications for the risk characterization been addressed? To*
 10 *what extent has variability adequately been taken into account?*

11
 12 We commend the EPA for progress in this arena. Use of the WHO guidelines is
 13 encouraging but needs more work to explain and clarify how it was adapted. Replace
 14 “uncertainty” with “imprecision” and add an assessment of impact of each source. A few
 15 key uncertainties are omitted: representativeness of the monitoring network (both the full
 16 network and the two subsets with 5-minute data), and the assumption that site-years are
 17 exchangeable. Re-evaluate the uncertainty characterization of the spatial representation.

18
 19 Discussion and response to Agency charge questions relating to characterization of health
 20 effects evidence and selection of potential alternative standards for analysis (chapters 3,
 21 4, 5)

- 22
 23 1. *The presentation of the SO₂ health effects evidence is based on the information*
 24 *contained in the final ISA for Sulfur Oxides. Does the draft REA accurately*
 25 *reflect the overall characterization of the health evidence for SO₂ contained in*
 26 *the final ISA? Does the Panel find the presentation to be clear and appropriately*
 27 *balanced?*

28
 29 The panel finds the presentation of SO₂ health effects evidence in the draft REA
 30 to accurately reflect the overall characterization contained in the final ISA for Sulfur
 31 Oxides. In fact, the style of presentation in Chapter 4 is too much like that of the ISA.
 32 Rather than listing the relevant studies in yet another chapter, the panel would prefer a
 33 more integrative approach to the presentation of health effects. Another concern relates
 34 to the discussion of the concepts of susceptibility and vulnerability in Chapter 3. In
 35 particular, while the panel appreciates the addition of Table 3-1, it finds the listing of
 36 specific susceptibility and vulnerability factors to be somewhat problematic. The
 37 discussion of susceptibility and vulnerability in the latest draft of the PM ISA is felt to be
 38 stronger and the panel suggests revising Chapter 3 along the lines of this discussion.

39
 40 One major issue that is not dealt with directly in the draft REA is the apparent
 41 inconsistency between the results of controlled human exposure and epidemiological
 42 studies. The former show brief exposures to SO₂ cause transient bronchoconstriction and
 43 respiratory symptoms and the latter observed associations between exposures to SO₂ and
 44 respiratory symptoms in asthmatic children after multi-day lags. The draft REA would
 45 be strengthened by acknowledgment of this apparent inconsistency and discussion of
 46 potential mechanisms by which brief exposures to SO₂ might lead to exacerbations of
 47 asthma a few days later.

- 1 2. *The specific potential alternative standards that have been selected for analysis*
 2 *are based on both controlled human exposure and epidemiological studies. To*
 3 *what extent is the rationale for selection of these potential alternative standards*
 4 *clear and sufficient to justify their use in the air quality, exposure and risk*
 5 *analyses? What are the views of the Panel regarding the appropriateness of these*
 6 *potential alternative standards for use in conducting the air quality, exposure,*
 7 *and risk assessments?*

8
 9 The presentation was generally sufficient and appropriate. A substantive case was
 10 made for consideration of a shorter-term standard that might obviate the need for the
 11 existing forms of the standard. Staff should seek continuity in approach and presentation
 12 across pollutants and documents (e.g., the susceptibility / vulnerability presentation in
 13 this document should incorporate recommendations made in a similar section in the PM
 14 document).

15
 16 The alternatives focus on the clinical studies carried out over many years and,
 17 particularly for this pollutant, form a justified basis for the selection of range of exposure
 18 for which susceptible individuals (asthmatics) are consistently responsive. Some
 19 discussion is needed that indicates why the risk assessment for this pollutant, in contrast
 20 to others, is limited only to health effects that are classified as sufficient to infer causality.
 21 Additional discussion indicating that there might remain even at the lowest levels of
 22 assessment a small fraction of potential susceptible subjects would inform the question of
 23 uncertainty as it applies to considering an adequate margin of safety.

24
 25 Discussion and response to Agency charge questions relating to characterization of
 26 exposure (Chapters 6 and 8):

- 27
 28 1. *Does the Panel view the results of the exposure analyses to be technically sound,*
 29 *clearly communicated, and appropriately characterized?*

30
 31 Chapter 6's approach to estimating 5-minute peak SO₂ levels is reasonable and
 32 clearly communicated, as is how air quality is adjusted to meet various benchmark levels.
 33 It would be good to move away from adjusting the health benchmark down such that you
 34 no long have to have the explanation of how the approach is equivalent to adjusting the
 35 air quality.

36
 37 The use of APEX and AERMOD are appropriate for conducting the exposure
 38 analysis. There is insufficient attention paid to characterizing potential biases in
 39 AERMOD results in the higher levels (95% ile and above), and how those impact the
 40 predicted exceedences of benchmark levels from APEX. The number of exceedences
 41 predicted by APEX is a very small fraction of the total number of total possible, and they
 42 represent the extreme high end of the distribution, and as such will be very sensitive to
 43 biases in the input air quality fields. This sensitivity has not been explored.

44
 45 A key weakness in this chapter is the lack of acknowledgement of the lack of
 46 evaluation of APEX. APEX is a complicated model, and not being able to thoroughly
 47 evaluate the results should be discussed. Further, the ability to simulate the 5-minute
 48 peaks should be assessed for Greene County where such observational data are available.

- 1
2 2. *The second draft REA evaluates exposures in St Louis and Greene County, MO. What are the views of the Panel on the approach taken? To what extent does this approach help to characterize the public health implications of the current standards? Does the Panel have technical concerns with this approach?*

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6
7 The committee applauds the inclusion of St. Louis in this analysis, thereby
8 capturing an urban area with a relatively high population density and moderately high
9 SO₂ emissions compared with other urban areas. Given that the dispersion model is the
10 only reasonable approach to extrapolating ambient levels between monitoring sites, there
11 is concern about the seemingly arbitrary adjustment of the non-point (area) source diurnal
12 emission rates in St Louis in order to achieve model closure. Therefore CASAC
13 encourages the staff to include a more extensive discussion of the agreement between the
14 model and measurements in this urban area.

- 15
16 3. *What are the views of the Panel regarding the approaches taken to model SO₂ emission sources? Does the Panel have comments on the comparison of the model predictions to ambient monitoring data?*

17
18
19
20 The panel generally supported use of both of the criteria that EPA chose to use for
21 selection of the 40 locations. Selection by the lowest mean adjustment factor means
22 selecting by relatively high SO₂ levels and thus offers EPA the opportunity to evaluate
23 the effectiveness of candidate alternative standards in places where standards may
24 produce the greatest benefits. It is also defensible to select counties with at least two
25 working monitors. This means that the analysis will be based on a more robust data set
26 than would be the case if only a single monitor were used to characterize the whole
27 county. One panelist offered another possible selection criterion-that is based on
28 relatively high values of the Coefficient of Variability statistic for the temporal variation
29 in SO₂. Some panelists expressed disappointment that limited practical use was made of
30 the 40 selected counties. The suggestion was made that if EPA's BENMAP model were
31 to be applied to these data in conjunction with the epidemiological literature for SO₂, then
32 all 40 Counties could be considered quite quickly for use in this document.

- 33
34
35 4. *What are the 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 characterization been addressed? To what extent has variability adequately been taken into account?*

36
37
38
39
40 The assessment of uncertainty and variability is extensive and staff has done a
41 good job in suggesting potential biases in the results due to the uncertainties discussed.
42 One uncertainty that is missing, and might be large, is the APEX results. As noted above,
43 APEX exposure results are not evaluated, and while it may be viewed that the uncertainty
44 in any one model component may be small or medium, the overall uncertainty of the
45 model results may be large, and significant biases may exist. Further, the model is being
46 used to predict extreme events which further challenge the system's (AERMOD +
47 APEX) capabilities. The implication of not being able to evaluate the system has
48 significant implications in how one might perceive the risk characterization results.

- 1
2 5. *What are the views of the Panel regarding the staff’s characterization of the*
3 *representativeness of the St. Louis and Greene County, MO exposure and risk*
4 *estimates?*

5
6 The characterization focused on time spent outdoors and distribution of asthma
7 prevalence. These were reasonably characterized although the higher prevalence of
8 asthma in the northeast suggests future analyses should focus on that region. The
9 discussion of representativeness of these two areas should also consider other spatial
10 locations in the U.S., regardless of presence of SO₂ monitoring data. An assessment of
11 the key features that distinguish St. Louis vs. Greene County may lead to insights about
12 other U.S. locations.

13
14 Discussion and response to Agency charge questions relating to characterization of health
15 risks (chapters 7, 8, 9):

- 16
17 1. *Based on conclusions in the ISA regarding decrements in lung function in*
18 *exercising asthmatics following 5-10 minute SO₂ exposures, we have adjusted our*
19 *range of 5-minute potential health effect benchmark values to 100 – 400 ppb. To*
20 *what extent does this range of benchmark values appropriately reflect the health*
21 *effects evidence related to 5-10 minute SO₂ exposures evaluated in the ISA?*
22

23 The authors have conscientiously used conclusions from the ISA to appropriately
24 adjust the range of five-minute potential health effect benchmark values. Potential health
25 effect benchmark values from 100 to 400 ppb have been carefully characterized in this
26 REA by using clearly appropriate parameters and clearly detailed applications of models.
27 The discussion was generally clear and compelling, but clarity of specific terminology
28 usage (such as “benchmark”) would be aided by a glossary for ready reference.
29

30 A consistent presentation, within and across documents (and pollutants), would
31 improve the document. (For example, 100 to 400ppb is presented for benchmark
32 consideration, but 50ppb effects are discussed in the epidemiology section, without any
33 integrating discussion; differing thresholds of causal evidence acceptability is used for
34 the SO₂ review compared to the PM document).
35

- 36 2. *Does the Panel view the results of the risk characterization in Chapters 7 and 8*
37 *and the lung function quantitative risk assessment in Chapter 9 to be technically*
38 *sound, clearly communicated, and appropriately characterized?*
39

40 Staff has done a comprehensive job of characterizing the health risks of SO₂.
41 However, some minor changes in the presentation would improve the credibility of the
42 work. Choosing FEV₁ and Sraw as measures of health effect in the quantitative
43 assessment while deciding against the use of respiratory symptoms should be better
44 rationalized. Why the focus of the risk characterization was on a single hourly peak
45 concentration at the exclusion of possible health effects caused by multiple peaks within
46 an hour needs to be better explained. It would also be helpful to include data supporting
47 the use of a concentration benchmark that is independent of physical activity (once
48 ventilation per unit body surface is above a threshold level).

- 1
2 3. *A quantitative risk assessment has been conducted with respect to two indicators*
3 *of lung function response in exercising asthmatics in St. Louis and Greene*
4 *County, MO. What are the views of the Panel on the approach taken and on the*
5 *interpretation of the results of this analysis?*
6

7 The EPA staff has done an excellent job at conducting the selected quantitative
8 risk assessment for the two chosen indicators in these specific two counties. The increase
9 to 40 Counties in the exposure assessment was seen as a substantial improvement over
10 the prior document. While the rationales for using St. Louis and Greene counties for the
11 analyses was deemed reasonable, the fact that these two counties appear to be in the
12 upper half of US counties (with respect to emissions, exposure, proximity to population
13 centers, etc) rather than in the extremes, raised some concern as to whether the full range
14 of the situations has been as fully characterized as possible. The “Additional
15 Representativeness Evaluation of St. Louis and Green County Air Quality” table
16 presented at the April 16, 2007 meeting was found to be helpful in addressing this
17 concern. However, some skepticism remained on the committee about the ability of such
18 exposure-effect models to specify human behaviors fully. While some members raised
19 concerns regarding the usefulness of applying the available SO₂ epidemiological studies
20 to the risk assessment, in agreement with the EPA’s choice not to do so, two panel
21 members expressed in their comments the opinion that the application of the SO₂
22 epidemiological study concentration-response coefficients to EPA’s BENMAP model for
23 the full 40 counties would provide another useful perspective that would strengthen the
24 risk characterization overall.
25

- 26 4. *What are the views of the Panel regarding the adequacy of the discussion of*
27 *uncertainty and variability? To what extent have sources of uncertainty been*
28 *identified and the implications for the risk characterization been addressed? To*
29 *what extent has variability adequately been taken into account?*
30

31 In general, the panel supports EPA’s efforts to characterize uncertainty. The
32 comments here are intended to guide EPA in more fully interpreting the uncertainty
33 characterization that has been conducted. We recommend that EPA revise the material
34 on uncertainty analysis taking into account the following points:

- 35 • A clear purpose should be stated for the assessment of uncertainty. One purpose
36 is to compare, on a relative basis, the uncertainty in the assessment endpoint
37 attributable to specific sources in order to identify and priorities needs for data
38 collection, research, or both, in order to reduce uncertainty. In this regard, the
39 qualitative uncertainty characterization can be used to infer a research agenda that
40 could be implemented to improve the state of knowledge for the next revision of
41 the standard five years from now.
42 • A second purpose of the uncertainty characterization is to make a judgment of the
43 weight of evidence supporting the assessment endpoint. As an example, there
44 could be an assessment the degree of confidence or certainty with which there is a
45 health effect and with which a particular alternative level, form, and averaging
46 time is protective of public health. As noted during the panel discussion, the EPA
47 staff should provide judgment regarding the implications of the uncertainty

1 assessment for the choice of the level, form, and averaging time in order to inform
 2 the decision making process.

3 While the 2nd draft of the ISA provides a fairly thorough qualitative
 4 characterization of uncertainty for a substantial number of inputs to the assessment, the
 5 final ISA will benefit substantially from synthesis of this information to support
 6 conclusions regarding identification and prioritization of key sources of uncertainty,
 7 development of an action plan to address these uncertainties (perhaps over a 5 year time
 8 period), and assessment of the implications of the uncertainties for use of the assessment
 9 results in regulatory decision making. With regard to the latter, it is possible to conclude,
 10 even when uncertainties are taken into account, that there are robust findings regarding
 11 health effects associated with short term exposures to SO₂. EPA staff should offer its
 12 judgment regarding the robustness of the technical analyses regarding air quality,
 13 exposure, and effects assessment in order to aid the Administrator in interpreting the
 14 assessment results. It is reasonable to point out that uncertainty typically exists in
 15 complex scientific assessments such as this, quantification of uncertainty is good
 16 scientific practice, that robust inferences are possible even in the face of uncertainty, and
 17 that there is a long track record of Agency decision making in the face of uncertainty.
 18 With regard to the latter, there are ongoing efforts within EPA, such as by the
 19 Probabilistic Risk Assessment (PRA) working group of the Risk Assessment Forum, to
 20 address how decisions regarding risk assessment is, can or should be made taking
 21 uncertainty into account.

22 There are various specific comments on the uncertainty assessments of Chapters
 23 7, 8, and 9:

- 24 • EPA has adapted a qualitative assessment methodology based on WHO (2008).
 25 EPA should provide an explanation of why a qualitative approach was selected.
 26 WHO (2008) proposes a tiered approach to characterizing uncertainty, which
 27 includes a qualitative tier and several quantitative tiers. Many panel members
 28 prefer to see quantitative approaches when possible, but recognize that qualitative
 29 approaches may be appropriate given assessment objectives. EPA should briefly
 30 discuss (perhaps one paragraph) the rationale for choosing to focus on a
 31 qualitative approach.
- 32 • EPA's adaptation of the WHO (2008) qualitative approach is a substantial
 33 modification of what WHO proposed. In particular, WHO recommends separate
 34 assessment of: (1) level of uncertainty; (2) appraisal of the knowledge base; and
 35 (3) subjectivity of choices. However, EPA appears to have collapsed these three
 36 attributes into a single category of judgments regarding low, medium, and high
 37 uncertainty. This implies a strong correlation between these three attributes,
 38 which may not be the case in all situations. Some explanation of how EPA's
 39 approach differs from WHO's, and the reason for the differences, is needed. This
 40 could be done in perhaps one to three paragraphs.
- 41 • EPA is using terms for "bias" and "uncertainty" to summarize qualitative
 42 assessments. However, these terms must be carefully defined. "Uncertainty" is
 43 often interpreted to include components of bias and imprecision, also referred to
 44 as (lack of) accuracy and (lack of) precision, or systematic and random error,
 45 respectively. The direction of bias is an important assessment and should be
 46 retained. It is unclear if "uncertainty" is another way of stating the effect of the

1 bias on the answer, or if it represents random error as distinct from systematic
 2 error.

- 3 • More clarity is needed to explain that the judgments of uncertainty are regarding
 4 the impact of uncertainty in each source on the uncertainty in the assessment
 5 endpoint. Hence, a clear statement is needed of what is the assessment endpoint.
 6 This should be footnoted in each table (Tables 7-14, 8-16, 9-10) so that the tables
 7 are self-documented. In the text, it would be useful to explain that uncertainty in
 8 the assessment end point can be conceptualized as the joint effect of the
 9 sensitivity of the assessment endpoint to a unit perturbation of an input combined
 10 with the range of uncertainty in the input, leading to a range of uncertainty in the
 11 output.
- 12 • EPA should tighten the connection between the summary tables and the text by
 13 using consistent terminology for labeling the sources in both the table and the
 14 text, to aid the reader in identifying and linking detailed explanations of each
 15 judgment with the summary information in the table. Furthermore, the addition of
 16 an explanatory comment column to Tables 7-14 and 8-16, such as was done for
 17 Table 9-10, would be helpful to the reader.
- 18 • In Chapter 7, there is material on pages 149-152 that is very difficult to follow.
 19 This material should be restructured as follows: (a) provide a clear statement of
 20 objective or purpose for the analysis; (b) provide a paragraph (or more, if needed),
 21 to explain the methodology used for the analyses; (c) provide a paragraph (or
 22 more, if needed) to convey the results of the analysis, the interpretation of the
 23 results, and their significance.
- 24 • EPA should review the various assumptions made in Chapters 7, 8, and 9 to
 25 determine whether any can be evaluated more quantitatively. For example, on p.
 26 145 of Chapter 7, the assumption that 5 minute and 1 hour average concentrations
 27 removed from the air quality data used for an analysis of the ratio of 5-minute to
 28 1-hour averages could be tested quantitatively. The marginal distribution of 5-
 29 minute concentrations that were removed could be compared to the marginal
 30 distribution of 5-minute concentrations that were retained to determine if they are
 31 similar – this could be done by comparing empirical cumulative distribution
 32 functions and possibly could include a chi-square test. A similar assessment
 33 could be done for the 1-hour average data.
- 34 • In general, Chapters 7, 8, and 9 include significant discussion of uncertainty.
 35 There is less discussion of variability. However, clearly variability is addressed
 36 throughout the ISA in various ways. Hence, it may be possible to add a paragraph
 37 or two in each chapter to place some emphasis on the aspects of variability that
 38 are addressed quantitatively in the assessment, as well as aspects of variability
 39 that are identified or characterized qualitatively.

40 Overall, the panel commends EPA for undertaking a systematic assessment of
 41 uncertainties.

42
 43 Policy Assessment (Chapter 10):
 44

- 45 1. *The policy chapter has integrated health evidence from the final ISA and risk and*
 46 *exposure information in this second draft REA as it relates to the adequacy of the*

1 *current and potential alternative standards. Does the Panel view this integration*
 2 *to be technically sound, clearly communicated, and appropriately characterized?*
 3

4 Overall, Chapter 10 was well written and the integration was, for the most part,
 5 clearly communicated and appropriately characterized. Staff did due diligence in
 6 consideration of the available evidence for consideration of current and potential
 7 alternative standards. However, the suggested decision process associated with
 8 considering an alternative 1-hr average standard and whether to change or revoke the 24-
 9 hr and annual average standards could be made clearer. The document seems to convey
 10 that a starting point for the decision is to determine the need for a 1-hour average
 11 standard, and set its form, level, and indicator. For indicator, SO₂ is clearly the preferred
 12 choice. The document implies that there may be a sequential process of deciding on
 13 whether there is a need for the 24 hour and annual average standards, given that
 14 compliance with the possible alternative 1 hour standard might imply 24-hour average
 15 and annual averages that are below the current standards.
 16

17 The document implies that if a 1-hour standard is to be developed, as
 18 recommended, that the choice of level should be informed by keeping in mind that health
 19 effects are associated with 5-10 minute exposures. Hence, the analysis supporting
 20 inferring a 1-hour average level that offers protection in terms of peak 5-minute average
 21 concentrations might be explained a bit more and perhaps augmented.

22 The final “Conclusions regarding level” (section 10.5.4.3) was internally
 23 somewhat inconsistent. The beginning statement in the section “provisionally concludes
 24 that the evidence and exposure and risk information reasonably support a 1-hour daily
 25 maximum standard within a range of 50-150 ppb” and concludes “if the alternative
 26 standard selected is not expected to prevent ambient SO₂ concentrations from exceeding
 27 the levels of the current standards, it would be appropriate to consider retaining the
 28 current NAAQS.” The evidence presented throughout the “Potential Alternative
 29 Standards” (section 10.5) and the language used clearly fall in support of a 1-hour daily
 30 maximum standard and the conclusion should reflect this.
 31

32 2. *What are the views of the Panel regarding the staff’s discussion of considerations*
 33 *related to the adequacy of the current standards? To what extent does the draft*
 34 *policy chapter adequately characterize the public health implications of the*
 35 *current standards?*
 36

37 All CASAC members agree that this chapter was well written and an excellent
 38 and welcome addition to the REA document. We also agree that the annual standard
 39 could be discontinued because of a lack of solid health effects data. The chapter does a
 40 good job showing that an annual standard is not justified (Tables 10.3 and 10.4 are very
 41 useful in this regard). Despite much discussion demonstrating the inadequacy of the
 42 current 24-hr standard, the text did not make a strong statement about whether the 24-
 43 hour standard should be retained, although the evidence presented (Table 10.3) was
 44 convincing that some of the alternative 1-hr standards could also adequately protect
 45 against exceedances of the current 24-hr standard. The panel seems to be in agreement
 46 that a 1-hour standard is the preferred averaging time and the text should clearly justify
 47 why a 1-hr standard would be preferred over a 5-minute standard. The chapter, while a

1 very good synthesis of the rest of the REA document, should expand its major
 2 conclusions.

3
 4 3. *To what extent does the draft policy chapter adequately characterize the public*
 5 *health implications of the potential alternative 1-hour daily maximum SO₂*
 6 *standards?*

7
 8 The authors of Chapter 10 have done an excellent job in distilling the information
 9 in the ISA and the REA. They show that the proposed alternative 1-hour daily maximum
 10 SO₂ standard is predicated upon the intersection of airway hyperresponsiveness [asthma]
 11 combined with exercise. The conclusions are presented in a systematic fashion and are
 12 coherent and compelling.

13
 14 The panel supports serious consideration of a 1-hour standard. We agree that the
 15 current daily and annual standards are not adequate to protect public health, especially in
 16 relation to short term exposures to SO₂ (5-10 minutes) by exercising asthmatics. But we
 17 note ambiguity as to whether or not the 1-hour daily maximum SO₂ standard should
 18 replace the 24-hour and annual standards. Deliberations should not be sequential. The
 19 merits of a single versus two or three standards should be presented. What staff
 20 recommends and the rationale for it should be clear.

21
 22
 23 4. *Staff believes that the evidence presented in the final ISA and the exposure and*
 24 *risk information presented in this second draft REA supports a potential*
 25 *alternative 1-hour daily maximum standard within a range of 50- 150 ppb. To*
 26 *what extent does the draft policy chapter provide sufficient rationale to justify this*
 27 *range of levels?*

28
 29 The Policy chapter clearly provides sufficient rationale for the range of levels
 30 beginning at a lower limit of 50 ppb. That said, however, the upper limit of this proposed
 31 range for the 1-hr standard, namely 150 ppb, may be too high and may not, therefore, be
 32 protective of certain sensitive populations. There are data, albeit limited, that show
 33 pulmonary functional responses at 200 ppb for short exposure periods and a 1 hr level of
 34 150 ppb may still allow peak excursions above this effect level. Thus, based upon this
 35 and the fact that ratios of 5 min to 1 hr concentrations may reach factors of 2 - 3, I
 36 recommend that the upper limit of the range for a 1 hr standard be reduced to 100 ppb.
 37

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Enclosure C:
Compilation of Individual Panel Member Comments