

**Comments from Members of the Chartered SAB on the draft *Report of the Risk and Technology Methods Review Panel (2-17-10 Draft)***

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## Comments from Lead Reviewers

### **Comments from Dr. David Allen**

Summarized below are my responses to the charge questions regarding the Draft SAB Review of EPA's "Risk and Technology Review" document:

*Question: Are the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?*

Response: The charge questions are adequately addressed.

*Question: Are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?*

Response: One of the issues addressed by the report is whether acute exposures can be adequately characterized by estimating the exposures associated with a 10-fold increase in the annual average emission rate (either actual or allowable). In general the report is supportive of this approach. For example on page 25 (Executive Summary), the panel states "...in the absence of chemical- and site-specific data, the use of the 10X screening assumption for petroleum refineries seems reasonable". Yet later in the document (Pages 85-87), the panel provides extensive discussion surrounding data that indicate that petroleum refineries can have episodic emissions that may be 1000 times annual average emissions, and these emissions may somewhat understate the true emission maxima, since the facility self reporting of episodic emissions discussed by the panel are time averaged. For example, if a facility reported a shut down episodic emission of X pounds over a 24 hour period (one shut down event), the hourly episodic emissions reported by Allen and co-workers (references cited by EPA and the panel) would be reported as X/24. Actual maximum hourly emissions would be higher since episodic emissions are, almost by definition, not constant. Given these data, it is unclear why the panel was supportive of the 10X assumption. This should be further clarified.

The panel also notes that the NEI "actual" emission estimates appear to be biased low (page 43, lines 17-19), and the panel should therefore make clear whether their recommendation for handling acute emissions is a 10X factor on actual or allowable emissions.

At several points in their review, the panel notes the uncertainties associated with performing dispersion modeling based on meteorological data that is remote from the facility undergoing residual risk analysis. For example, in the petroleum refinery case studies, the meteorological data that were used came from Galveston Island. The panel notes the uncertainties that this can introduce, but this point deserves increased emphasis in the Executive Summary and possibly in the letter to the Administrator.

*Question: Is the Committee's report is clear and logical*

Response: In general, the report is clear and logical, however, two structural changes could improve the clarity of the report:

1. The report both praises the EPA's efforts in the RTR document (e.g., page 14, lines 1 and 2), and raises multiple substantive issues. For the most part, the panel is supportive of the modeling tools and frameworks used by the EPA, but is critical of

- the input data into the models (e.g., meteorology and emissions data). More clearly differentiating between uncertainties associated with modeling frameworks and required model data would improve the clarity of the report.
2. A roughly 80 page report has an Executive Summary that runs to almost 20 pages. The Summary should be condensed.

A few minor clarifications would also be valuable

3. Page 59, line 1, it is not clear why the emissions are implausible
4. Page 69, line 10, and at several other points in the document (Page 74, line 30), the panel makes very specific recommendations that need justification. (e.g., “if [the dose response value] was developed more than 7 years ago, a literature review should be performed” – why 7 years?)

*Question: Are the conclusions drawn or recommendations provided supported by the body of the Committee’s report?*

Response: With the exceptions noted under the second question, the recommendations are supported by the body of the report.

## Comments from Dr. Timothy Buckley

### 1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

In general, the subject report was responsive to the charge questions. However, within the Executive Summary, the following points of clarification are suggested.

#### Charge Question #1:

- As I read the first charge question, EPA is looking for advice on the usefulness of a variety of means for evaluating emission estimates. My read of the Review Panel's report is that they answered a slightly different question which is what is the best method for estimating emissions for purposes of risk assessment. The charge question is oriented toward the process of evaluation whereas the Panel response is oriented toward the outcome of the analysis.
- Within charge question 1A, EPA asks for suggestions as to "ways that we can develop similar analyses for other HAPs and source categories" as they have done with benzene. I do not see that the Panel provided a response to this particular question.
- Charge question 1B asks whether "the approach used to estimate dioxin and furan emissions from Portland cement facilities represent the best available methodology . . ." I suggest the following edits to the Panel's response to provide a more direct response.

Executive Summary (pg 16): The Panel recommends that residual risk assessments be conducted using the current source-specific National Emission Standard for Hazardous Air Pollutants (NESHAP) allowable emission rate in combination with each facility's maximum permitted production rate. It is the Panel's assessment that this approach provides the best available methodology because . . . This should be done whenever NESHAP emission limits have been set for specific hazardous air pollutants. In particular, using estimated emissions that exceed the NESHAP limit is not appropriate for the residual risk assessment. Because allowable limits were not modeled for dioxin and furan (D/F) emissions from Portland cement facilities, the Panel does not believe the approach used in the case study represents the best available methodology in support of a residual risk analysis. There is no need to estimate D/F emissions for Portland cement facilities, when allowable limits exist.

#### Charge Question #2:

- Within the Executive Summary (ES), the report does not provide a response to the question whether EPA's analyses support the practice of "using facility-supplied meteorological data . . .". [the Panel justifies their lack of response on page 63, footnote 10]
- I suggest the following edits to the ES (pg 19) to sharpen the Panel's response to the charge question relating to "(4) omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling".

The results of the Agency's analysis of omitting HAP *decay* and deposition in risk assessments do support this practice and could be applied to other source categories. However, the same can not be said for atmospheric chemistry since it is possible that secondary HAP *formation* could be

significant for some source categories. Further sensitivity studies of secondary HAP formation would be required to rule out the necessity of including complex photochemical modeling for future HAP risk assessments.

- For the question “(5) using block centroids as surrogate exposure locations for these case studies?” it is unclear how the Panel’s ES recommendation differs from what EPA provided in their analysis Section 4.8 and Appendix M.

Charge Question #4A.

- Within the ES, I do not see a clear or direct response to EPA’s charge question: “Does our process of estimating inhalation exposures adequately support regulatory rulemaking?”

**2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee’s report.**

No technical errors were observed in the Panel’s report. Omissions are identified above relating to specific charge questions.

**3. Whether the Committee’s report is clear and logical.**

The report was clear, logical and well written.

**4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee’s report.**

The report recommendations were will supported by the body of the report.

## Comments from Dr. Deborah Cory-Slechta

### Comments on Risk and Technology Review Risk Assessment Methodologies

First, it was clear from reading the charge questions that this Committee was presented with a very broad and multi-faceted set of charge questions to address. I congratulate the Committee and its Chair for producing in this document, a response that in general does a commendable job in responding to the question. Comments that I have are actually very brief.

1. If possible, I would highly recommend changing the title of this document/review which makes little obvious sense. It could use some clarification and brevity, but this may be outside the purview of the committee.
2. In general, the document does provide answers to the set of charge questions that were posed, albeit with some unevenness. That unevenness in some cases directly reflects the difficulty of the question and the lack of any clear options with which to address it. However, one section which stood out a bit, at least to this reviewer, was the response to charge question 3a, in particular the sections entitled “Analysis of Unassessed HAPs’ and ‘Incorporation of HAPS lacking dose-response Values’. The responses in these two sections seem rather vague and there is what appears to be more ‘filler text’ than concrete advice. This again may reflect the absence of any particular advice that can be given, but perhaps that ought to be directly stated.
3. Recognizing all too well the difficulty of extracting the most salient points from such a broad set of charge questions and to accommodate all of those within the prototype 2 page letter, the one point that didn’t appear to make the executive summary was the extent of cautions about the TRIM model.
4. P. 88, lines 11-19. It seems a very major conclusion to state that summing acute hazard quotients by target organ would not be necessary. It is based on the preceding phrase that simultaneous release under adverse meteorological conditions would be very unlikely. Certainly some reference or support for that rationale should be provided given that multiple effects on the same target organ should be of significant concern in the context of cumulative risk.
5. Some other corrections/clarifications:
  - p. 44, lines 14-15: ‘using revised emission data that were revised...’
  - p. 62, line 10 ‘permitting to utilize five years...’
  - p. 69, line 10, ‘developed more than 7 years ago...’ what is the basis for a figure of 7 years?
  - p. 70 lines 28-29 through p. 71, lines 1-2. This needs re-writing, the point(s) are not clear.

## Comments from Dr. George Daston

Overall, I found this report to be well written, with the conclusions largely supported by the information contained in the review. It is clear that the review panel has a great deal of expertise in risk assessment methodology and their comments will improve an already good process developed by EPA staff.

I was asked to address four specific questions as part of the quality review.

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Question 1: The charge questions posed to the review panel were all adequately addressed in a very transparent way. Responses and recommendations were organized in a way that makes it clear which recommendation addresses which charge question.

Question 2: I found no technical errors or omissions in the report, but there are two recommendations that should be justified a little more fully. The first is the recommendation on p. 21 (second paragraph) and pp. 72-73, that the issue of children's hazard be represented as an additional uncertainty in the dose-response assessment for non-cancer and cancer hazards. Some justification is provided for why genotoxic carcinogens might be evaluated with a child-specific assessment factor, but the justification for how EPA should characterize and quantitate this uncertainty is inadequately described. I believe that there is EPA guidance on how to evaluate cancer dose-response for risk in children; the review panel should evaluate whether this is adequate for the risk evaluation methods described here, and if so, should recommend that it be followed. As for non-cancer dose-response, it is also my understanding that EPA has developed guidance, at least in some contexts (e.g., chemicals regulated under the Food Quality Protection Act) for how to evaluate risks to children's health. Again, I would expect that this would be the procedure recommended by the review panel unless they have explicit reasons to recommend something different.

The discussion of AEGLs and other acute guidance values on p. 22 and pp. 74-76 and ACGIH TLVs on p. 70 recommends that EPA incorporate an additional uncertainty factor of 3 to these values to cover the instances in which those values are based on LOAELs. In effect, the factor of 3 covers the uncertainty in the LOAEL-to-NOAEL extrapolation. I do not think this is the best recommendation that could have been made. Modern risk assessment practices at EPA (e.g., for IRIS assessments, use benchmark dose methodology to calculate a point of departure for risk assessment, a procedure that renders moot the LOAEL-NOAEL extrapolation. I believe that this would be a preferred approach. Furthermore, it should be a reasonably easy matter to determine which guidance values are based on LOAELs such that any adjustments could be limited to these.

Question 3: I found the report to be clearly and logically presented. It was a pleasure to read.

Question 4: In all but one instance, I found the conclusions of the report to be well documented and supported. The only conclusion that I have concern about is the one regarding the use of maximum allowable emission levels (MACTs) vs. emission estimates based on actual data (pp. 42-50). The reason given is that the reported emission values can be uncertain and may in some cases be underestimates of actual emissions. While I appreciate the desire to be conservative, I believe that the review panel is making a recommendation that does not serve the desired purpose of the residual risk calculations. My understanding is that the purpose of the evaluations is to determine whether emission control technologies are doing their job, and if so whether (and how much) risk still exists to the public or environment. This purpose is best served by using the estimates of emissions, however imperfect. It is possible to identify at least some of the conditions under which emissions are underestimated, and these can be accounted for, at least partially. Evaluating residual risks by using pre-established MACT levels does serve a purpose, but it is really an evaluation of whether currently the MACT levels are adequate to reduce emissions to levels with negligible risk, a distinct question from what was posed.

## **Comments from other SAB members**

### **Comments from Dr. Terry Daniel**

#### **SAB Review of EPA draft RTR**

1. **YES**, the original charge questions were adequately addressed.
2. **NO**, there do not appear to be any substantive technical errors or omissions or issues that are inadequately dealt with in the Committee's report.
3. **YES**, the Committee's report is clear and logical.
4. **YES**, the conclusions drawn and recommendations provided are supported by the body of the Committee's report.

An issue that arises in several places in this review is the degree to which "exposure" factors are addressed and the weight assigned to them in the overall risk assessment/characterization is considered. For example, it is suggested that for some purposes using census block centroids as the sampling grid may need to be replaced by or enhanced by samples based on the locations of individual residences. In several places the need for consideration of special vulnerable populations (e.g., children) is noted. In addition, daily (or other schedules) of behavior relevant to exposure are noted as potentially important factors. For the most part, however, when exposure factors are noted as not having been given adequate attention in the draft RTR, the review concludes that this is acceptable because relevant data are either not available or are out of date. In contrast, in the several cases where data about concentrations of hazardous chemicals (due to emission rates or dispersion factors) or precision of dose-response models are noted as limitations or contributors to undesired uncertainties, the review strongly recommends that EPA undertake literature reviews and initiate research to increase measurement/estimation precision and to update models. Why is there not a similar call for reviews, research and updates of data about relevant exposure factors? Is it because increasing precision or certainty of concentration or effect parameters would provide "bigger bang for the buck" in protecting human health or the environment?

The importance of exposure factors seems likely to increase as risk assessments become more place-based, more concerned about special vulnerable populations, and more attentive to cumulative risks and risk interactions. That is, the particular mixes of multiple hazardous chemicals intersecting with distinct populations having variable vulnerabilities is likely to be more variable (in time and space and concentration/composition) so that a more refined assessment of exposure variables will become ever more important in assessing and characterizing risks. Similar considerations would indicate that ecological risk assessments will need to attend more to the special characteristics and conditions of specific ecosystems exposed to specific concentrations/mixes of hazardous materials

### **Comments from Dr. Rogene Henderson**

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The report was quite clear in stating each charge question and addressing it with specific comments.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I am not an expert in this field but I did not note any technical errors or omissions.

3. Whether the Committee's report is clear and logical.

The report appeared logical to me.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The recommendations were supported by the body of the report. The letter reflects the major points made in addressing each charge question as described in the Executive Summary.

## Comments from Dr. Bernd Kahn

### SAB-RTR Review

The review is excellent. A few comments follow:

p.1, l.20: On line 12, 'with' is in place of the colon before 'Case'; also p.13, l.7, and p.29, l.6.

p.12: Missing acronyms include

- HQ p.92, l.23
- MTBE p.52, l.17
- NIOSH p.75, l.7
- OSHA p.76, l.8
- POM p.52, l.10
- STEL p.75, l.5
- TEQ p.55, l.22

p.24, l.10: Skip line for new paragraph; also p.81, l.27.

p.31, l.17: Who is the 'we'?

p.58, l.1: Useful models are reported in early EPA NESHAP studies for the same radioactive effluent from coal-fired power plants and from elemental phosphorus plants, for which findings are summarized in Report EPA 520/1-84-022-1/2 in Volume 2, Sections 4 and 6, respectively. The radioactive isotopes of interest are gaseous Rn-222 and Po-210, and particulate U-238, Th-232 and radioactive progeny. Note, however, that the radioisotope specific activity of deposited or near-ground airborne particles may be essentially the same as in the ambient soil.

p.65, l.21: Although local deposition has only minor impact on distant chronic exposure, air scavenging by rain washout has been shown to be important in radioactive effluent studies for the air-to-ground pathway with regard to chronic exposure via food and feed and for acute exposure associated with rainfall.

**Comments from Dr. Nancy Kim**

1. Were the original charge questions to SAB Committee adequately answered?  
Yes.
2. Were there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?  
No.
3. Was the Committee's report clear and logical?  
Yes. I thought that section 4.0 was well laid out and organized. Section 3.0 seemed somewhat long.
4. Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?  
Yes.

## Comments from Dr. Judith Meyer

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

They are adequately addressed.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

Not that I could discern.

3. Whether the Committee's report is clear and logical;

In general yes.

a. p. 13, line 27 -30: I think a clarification of what is meant by "residual risk" is needed; how does a residual risk assessment differ from ordinary risk assessment? It seems that the two terms are used interchangeably at several points in the document, so I am confused. It is finally explained on p. 29, but some explanation is needed much earlier in the document. It seems as though when the term "risk" is used in this document, the panel really means the "residual risk" that is specific to the Clean Air Act requirements. If so, that needs clarification.

b. This is a very long and detailed report with many recommendations. The recommendations are often buried in the text. Did the panel consider highlighting or bulleting them? It may not be feasible, but it would make finding recommendations easier.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

In general, yes.

a. p. 21: Define ATSDR MRL when first used. That recommendation in the Executive Summary comes out of the blue with no explanation of context.

b. p. 84: The recommendation with respect to particle-bound HAPs seems important enough to be included in the Executive Summary, yet it is not there (unless I missed it). The potential importance of particle bound HAPs identified in the discussion of the ecological risk assessment, further enhance the importance of this observation and recommendation and make it even more important to include in the Executive Summary.

### Editorial comments

1. Letter, p. 2, line 14: spell out HAP when first used

2. p. 13, lines 17-18: Details of the quality review process are not usually a part of these reports. That sentence could be eliminated, especially in the Executive Summary. Too much detail!

Lines 25-26: Don't need the sentence that begins with "The responses that follow...." It is obvious.

3. p. 22: Define LOAEL and NOAEL when first used. Also it is not clear what the difference is between AEGL-1 and AEGL-2; and between ERPG-1 and ERPG-2.

4. p. 26, lines 27-28: some examples of the kinds of site characteristics you have in mind would make this recommendation less vague.

5. p. 41: Don't repeat the entire charge question including the background information! It makes the report have too many redundancies. I suggest eliminating the previous section where

ALL charge questions are listed, and instead put each charge question at the beginning of each section where it is answered. It doesn't need to be in both places, and it is easier for the reader to follow if the question is just before it is answered.

6. p. 86, lines 1-2: these are printed over in my pdf, so I have no idea what they say.

7. p. 92, line 27: the "prior studies" require a citation.

8. p. 94: Although it is valuable to have this list of references, it is really bizarre to have them listed in the text of the report. In general, I found the use of footnotes for citations unusual for an SAB report. Why not just have a literature cited section at the end of the document, and cite (author, date) in the text rather than using footnotes.

9. p. 100, line 15: "IN Harris county..."

10. p. 97, line 24: Somewhere in the response to this charge question, reference needs to be made to the existence of an appendix with more detailed editorial comments on the risk characterization section. This would be a good place to do that.

## Comments from Dr. Duncan Patten

1. Are the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The original charge questions are well covered by the report, although in many cases they were not questions but rather "requests" (see comments below).

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

There appear to be no technical errors or omissions, although this is not an area of my expertise and others can better answer this.

3. Is the Committee's report is clear and logical?

There is some inconsistency in how the committee responds to the charge questions. In some places they as in Charge question 1, the committee responds to separate restated components of the question and in others, such as Charge question 3 they respond without restating the question. Consistency would help....

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

As far as I can tell, yes.... the recommendation for developing a new document with actual protocol steps and using this one as background is fully justified and appropriate.

Other comments: There should be some consistency between what is requested as stated in letter to administrator, and what the charge questions request, although as pointed out below, some of not questions but requests. The committee uses a general set of requests in the letter and Executive Summary that do not wholly cover the charges.

I've brought this issue up in other requests for review and do so here. When SAB is requested to review a document and the EPA office requesting it uses charge questions, they should use questions rather than requests. For example, in Charge Question 3, the Charge Question "requests" the review committee to suggest what additional material should be in the report rather than asking for critique of what is in the report and then addressing omissions if necessary. These types of Charge "Questions" appear to be an admission of the authors of the original report that they have not fully done their homework and are asking the review committee to help them rewrite the report. Suggestions for how to rewrite and what to include in a revision should result from a review of a fully complete and documented draft which may have need of improvement.

**Comments from Dr. Steven Roberts**

The panel was asked to respond to seven charge questions regarding this report, covering an array of topics. The panel report is well organized, thorough, and well written. The bases for conclusions and recommendations are clearly explained. The Executive Summary is a concise yet inclusive discussion of the panel's findings. Key points are adequately captured in the letter to the Administrator. The panel appears to have done an excellent job, and I have no suggestions for changes or editorial comments. Briefly, responses to the quality review questions are: 1) The charge questions were adequately addressed; 2) I found no technical errors or omissions in the report or issues that were not adequately dealt with; 3) The report is clear and logical; and 4) The conclusions and recommendations are supported by the body of the report.

## Comments from Dr. Amanda Rodewald

The committee prepared a very thorough report that contains a tremendous amount of useful information.

1. are the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

As a whole, yes. However, there were times when it felt that the reader had to intuit the actual answer based upon the information presented in the response (e.g., response to Charge 1A). I think that some reorganization would improve the usefulness of the responses (see comments in #3 below).

2. are there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

No.

3. is the Committee's report is clear and logical;

In some places, the organization of (not content of) the text made the document confusing and difficult to read. I highlight examples below:

In the Charge Questions section, I was confused by the placement of the text boxes that contained the charge questions 1A – 1D. At first it seemed that the text on pages 32 (lines 26-31) and 33 (lines 1-24) might be in response to the charge question 1A that *followed* on page 33 lines 25-30. The same is true for the subsequent charge questions. I spent time trying to sort out what I was reading (i.e., questions and responses?), and I did not completely figure it out until I saw Section 4.0. I think both the text boxes and the unusually long charge questions (9 pages) contributed to my confusion.

The structure of “Recommendations related to Charge 1A” (page 51) was a bit awkward given that the first actual recommendation was not articulated until page 53. Perhaps the recommendations can precede the justification/critique. Also, if the actual recommendations were bolded or otherwise highlighted, the reader would not have to search for them.

Likewise, in the panel response to Charge Question 1B (page 55), it seemed as though the question was not directly answered. The response included a lot of important and useful information, but the reader needed to synthesize the information in order to construct a concise answer. Perhaps the question can be succinctly answered in the initial sentence or two and then the elaboration/supporting details can follow the answer.

In the panel response to Charge Question 1C (p. 58), the first question was not answered until the middle of the second paragraph (line 12). I suggest leading with the answer and then supporting that position in subsequent text.

These same comments can be applied to other response sections. Overall, I think that a concise answer should lead the response and that can be followed by support. In the current document, I perceived the answers to be buried in text and difficult to quickly extract. The response to Charge Question 3A (page 68) and 3B (page 74) are great examples of first providing the simple answer and then qualifying it.

4. are the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Yes.