

**Comments from Members of the Chartered SAB on the SAB Draft Report:
Review of EPA’s Screening Methodologies to Support Risk and Technology Reviews
(RTR): A Case Study Analysis (4-25-2018)**

List of comments received

May 24, 2018

Comments from Lead Reviewers.....	1
Comments from Dr. Sue Marty.....	1
Comments from Dr. Kenneth Portier.....	2
Comments from Dr. Tara Sabo-Atwood.....	7
Comments from other SAB Members.....	10
Comments from Dr. Deborah Hall Bennett.....	10
Comments from Dr. Robert Blanz.....	11
Comments from Dr. Todd Brewer.....	13
Comments from Dr. Alison C. Cullen.....	13
Comments from Dr. Otto Doering.....	13
Comments from Dr. Susan Felter.....	14
Comments from Dr. John Graham.....	15
Comments from Dr. Michael Honeycutt.....	17
Comments from Dr. Merlin R. Lindstrom.....	17
Comments from Dr. Kristina D. Mena.....	17
Comments from Dr. Larry Monroe.....	19
Comments from Dr. Thomas Parkerton.....	20
Comments from Dr. Robert Phalen.....	25
Comments from Dr. Richard Smith.....	26
Comments from Dr. Jeanne VanBriesen.....	27
Comments from Dr. Donald vanderVaart.....	28
Comments from Dr. Kimberly White.....	29
Comments from Dr. S. Stanley Young.....	30

Comments from Lead Reviewers

Comments from Dr. Sue Marty

1. Were the charge questions adequately addressed?

Yes, the charge questions were addressed in a logical order. The letter to the EPA Administrator followed the sequence of the report and captured the main points covered in the report summary. However, I agree with the recommendations of the SAB. It is reasonable to target this document to risk assessors instead of general reviewers. As models become more complex, there are fewer experts focusing on these models and their applications. Therefore, the report would be most effective if targeted toward risk assessment practitioners with a more thorough presentation of the RTR risk assessment screening approach. As proposed by the SAB, more detailed case studies would be a valuable addition with documented decision logic that is clearly explained (reproducible results should be an expectation). Model assumptions should be clearly stated and the rationale to move from one Tier to the next should be transparent.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

The SAB's review of the EPA report was comprehensive and I agree with many of their suggestions. Below are a few comments to highlight some areas that may require more emphasis.

The goal to screen facilities efficiently to allow EPA to focus time and resources on sites of greater concern is worthwhile. A three-tier multipathway approach seems appropriate. However, the EPA may need to decide *a priori* the level of precision that is needed in the early tier screening models. There is a balance required to keep a screening level model useful – i.e., the model must work sufficiently to meet screening needs (i.e., be protective) with minimal effort – if it is too labor intensive, the value of screening is lost. The SAB made a number of recommendations in its report; it may be useful to examine the effort required to implement some of the proposed changes versus the improvements in screening. Perhaps sensitivity analysis of model variables can shed light on this. When evaluating the performance of the screening level model, consider examining the prioritized source list. If refinements to the model do not change the order of the prioritized sources, then the refinement (and additional work) may not be needed.

Validation of model outputs may be challenging. In many cases, field data to truth screening model results may be unavailable and if present, these field data may represent limited conditions/scenarios. Furthermore, while it is a noteworthy objective to validate the screening level dispersion model (i.e., TRIM.FaTE) against the more established dispersion model (i.e., AERMOD), this may be difficult to do in practice, particularly given dynamic environmental conditions. If one assumes that the AERMOD model is correct and accurate, what level of precision is needed in the screening level model? Is an order of magnitude sufficient? Reliability (or limitations) of TRIM.FaTE model should be demonstrated for a variety of

scenarios.

While TEFs work well for dioxins and carcinogenic polycyclic aromatic hydrocarbons (PAHs), I agree with the SAB that more information is needed on the toxicity equivalency factor (TEF) approach for compounds with no known carcinogenic potential. TEFs require the use of the same endpoint to determine relative potency; thus, it is uncertain how TEFs were determined for some polycyclic organic matter/polycyclic aromatic hydrocarbons (POMs/PAHs), which are not mutagenic/carcinogenic as these chemistries are complex and variable. Perhaps the EPA can provide a more detailed description of “professional judgement” or perhaps prepare a short guidance for determining these TEFs.

One point that is mentioned by the SAB, but may require greater emphasis is the issue of conservative model inputs. Probabilistic analysis using distributions of input parameters and estimated confidence limits seems appropriate; however, caution is warranted so that the EPA does not magnify ‘overly conservative’ assumptions (e.g., multiple 90th percentile distribution estimates coupled with high fish ingestion rates by fishermen and their families, overestimated fish bioaccumulation, etc.). While some level of conservatism is needed, overly conservative assumptions mean that too many facilities will be identified as “sites of concern” and EPA’s ability to focus on sites that pose a greater risk to public health may be diminished. The use of sensitivity studies to identify key input values will improve models and prioritize information collection.

The EPA should develop a plan to collect screening data over time to determine the efficacy of the screening approach and if there are some source categories that are generally of limited concern. For other source categories, are there additional data that will refine screening methodologies to allow greater differentiation between sites of greater and lesser concern? With analysis of these data, best practices on model parameterization can be determined.

3. Is the draft report clear and logical?

Yes, in my view, the report is well written and well organized.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes. While there is a reminder to the SAB to allow some latitude in EPA screening approaches (i.e., support both accuracy and efficiency), the SAB made numerous constructive recommendations for EPA consideration.

Comments from Dr. Kenneth Portier

Overall, the Draft SAB report responds to the charge questions posed by the EPA.

Some revision is needed to ensure that the SAB answers to the questions and recommendations are presented clearly.

Recommendation for areas of improvement.

- Discussion for each of the charge questions would be greatly improved by providing the SAB finding on each charge question as the first paragraph of each response. “The SAB finds that”.
- Include a bulleted list of key recommendations, suggested recommendations and future needs at the end of the discussion text of each question (see for example the recent RDX Advisory Report).
- The phrases “The SAB notes...” and “The SAB suggests ...” are used often in the text. It is not clear whether statements following these phrases point to a key recommendation, a suggested recommendation or a topic for future study. Should use the phrase “The SAB recommends...” or “The SAB recommends for future study...”.
- For many questions, the report notes the SAB finding is that the “methodology and ... revisions ... are reasonable ... and justified...” whereas the questions posed by the Agency are about the appropriateness of the methodology. Does Reasonable + Justified = Appropriate? If so, then maybe adding “hence the SAB finds the methods/revision appropriate” to finding statements which will ensure readers understand that the SAB is answering the question asked. (see, for example page 24, line 12-13).
- Replace statements “EPA should...”, “the SAB suggests...”, or “the SAB recommends that EPA consider the use of...” with “The SAB recommends that EPA ... do/implement ...”. EPA always has the option to ignore SAB recommendations, whereas we must be clear in our recommendations.

1. Were the charge questions adequately addressed?

Charge Question 1.

A clear answer is difficult to find.

On page 10, lines 30-31 the SAB agrees the approach is “reasonable and logical” (hence “appropriate”?). At the same time, the SAB “concur[s] that it (*Tier 1*) is conservative”. It is not clear from the text whether the SAB finds this does so at an “appropriate” level. Based on the discussion on the effectiveness of the screening methodology, I (the reader) conclude that the finding is that “the SAB cannot confirm” the methodology is appropriate. The key recommendation is that “An analysis of the tier-specific screening efficacy should be conducted for each source category” through a “ground-truth” evaluation.

The bulleted items in the additional comments and recommendations section along with the conclusions in the discussion text should be incorporated into a bulleted list of key recommendations, suggested recommendations and future needs - making it clearer which are most important for the Agency to address first.

Charge Question 2.

A clear answer is difficult to find.

The report documents deficiencies in the approach and makes recommendations for improvements, but it is not clear whether the panel finds these deficiencies produce a REF methodology that does not appropriately account for differences in environmental fate and transport for POM and dioxin congeners. There is some discussion about data rich versus data poor chemicals, but again it is not clear that the methodology may work for data rich chemicals but not work for data poor chemicals.

If I had to hazard a guess at the panel's finding (*which a reader should not have to do*), I would say they find the methodology does not appropriately account for differences in... in its current form.

Charge Question 3.

The panel report discusses all three parts of this three-part question but in only one part does the draft report present a clear finding.

Subsection headings could be utilized to separate out the three parts as is done for charge question 4.

The draft report notes general support for the assumptions on human fishing behavior and offers recommendations for improvements. Is “generally supportive” the same as a finding of “appropriate”? (page 17, line 22).

The report finds an inability of the panel to answer the question of appropriateness of the assumptions about PB-HAP deposition. They point to inadequate or missing information around the reliability of the TRIM.FaTE air concentration and deposition estimates for a range of representative scenarios. It is not clear whether the recommendation is to replace TRIM.FaTE with AERMOD or that TRIM.FaTE is adequate but just needs better (parameter and assumption) documentation and a rigorous performance evaluation. Clarify the recommendation here. Refer to Page 20, lines 34-40 where the recommendation is clearer.

The SAB expressed concerns with the appropriateness of assumptions on the sustainability of fish population in ponds and lakes, finding that the fixed values used for some parameters cannot adequately represent the wide range of occurrence in actual lakes. The SAB recommends EPA provide better documentation and justification for these assumptions but does not suggest ways to improve the methodology. (*Did the panel discuss a probabilistic approach for this issue?*)

On page 18, lines 25-29 there is discussion on how the panel struggled with understanding some of the RTR modeling inputs/assumptions. This paragraph should be expanded to provide more detail on which modeling inputs or assumptions, other than the ones already discussed in the text, need better descriptions and/or illustration. Provide recommendations on how the EPA report appendices should be enhanced to be more complete.

Charge Question 4.

The report does not offer a clear finding as to the appropriateness of the methods used for

evaluation of these data. The report does comment on the adequacy of data sources, types of data, and methods of obtaining data and from these comments one might infer that the SAB did not find the methods fully appropriate.

Lake data – The discussion suggests the SAB is not totally happy with the method used to evaluate lake data (e.g. some data too time-intensive to acquire, inclusion/exclusion too subjective or inadequate). If this is a true statement, then “The SAB finds the methodology used... is inappropriate”. Good recommendations on where to get better and more cost-effective data are provided.

Plume rise – Recommendation that EPA consider use of other plume-rise models suggests the SAB concluded the method of evaluating plume rise models in the EPA report is inappropriate. Is this correct? What models other than AERMOD should be considered?

Time series meteorological and plume-rise data – The caution on oversimplification of complex atmospheric processes and potential unrepresentativeness of data from nearest met station suggests inadequacies in the method for evaluation of these data as presented in the EPA document. The SAB concluded that hour-by-hour response data is not justified but there is no discussion on what other time metrics might be better.

The bulleted statements at the end of this section should be expanded upon. The first bullet discusses the “quantity of emissions” from the NEI but the subsequent statements seem to address the “representativeness” of these data. The second bullet recommends a sensitivity analysis but offers no further details as, for example, where might be good starting points for this task.

Charge Question 5.

The report clearly and concisely answers these questions. Recommendations are clear.

Charge Question 6.

The SAB report clearly answers these questions. Recommendations are not clear. See Page 24, lines 31-32 and 39-41; Page 25, lines 1-2. Bulleted comments, page 25, read as recommendations for improvements and should be so labeled.

Charge Question 7.

I think I understand what the report is concluding. “The RTR approach/tool is appropriate.” On the other hand, the SAB is recommending a different procedure for identifying urban from rural impacting facilities, or for partitioning impacted areas to urban or rural fractions (setting the “model domain”). This is a **KEY RECOMMENDATION** and should be identified as such. Two procedures, a “best practices” [page 26 and an “alternative” [page 27, lines 16-20, are discussed. When would the alternative be used instead of the “best practices” procedure? Is this a cost of implementation issue?

Charge Question 8.

“The SAB finds the EPA report does not provide enough information about the tool, especially regarding criteria that would be used to determine the number and placement of new receptors.” [page 28, lines 19-20 Reading the discussion, it is clear that the issue is not with the “Tool” but with the instructions/procedures (*the method referred to in the question*) for use of the Tool. My conclusion is “The SAB finds the method inappropriate.”

Many excellent recommendations and suggestions are made, but it is difficult to decide which is which. Page 28, line 31 to page 29, line 2 offers a good suggestion which would be clearer if written as a recommendation. The text on page 29, lines 4-11 discusses what “can” be done. I suspect EPA staff are aware of what can be done but are more interested in what the SAB “recommends” they actually do in this situation.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

No technical errors or omissions were noted. In a couple of places, as identified above, additional justification for a recommendation/suggestion is needed.

3. Is the draft report clear and logical?

The body of the draft report is logical in its flow, but question discussions, conclusions and recommendations could be better presented as indicated above.

Alignment and consistency of the Executive Summary:

The executive summary will benefit from a rewrite that reflects the flow of the full report. The answers to the specific questions asked by the EPA are interspersed with recommendation statements for actions to improve the current methods and statements of needed future research. Findings and recommendation are not fully summarized.

By clearly stating the panel findings and listing key recommendations for each charge question in the body of the report, it will be easy to incorporate these same statements into the executive summary.

Nothing precludes the use of sub-section headings (see list page 2, lines 33-37 as potential headings) and bullets in the executive summary.

Page 3, lines 5-23 – These two paragraphs do not find corresponding text in the body of the report. No discussion on the primary audience for the document. Few comments on missing or inadequate case studies. No discussion on compiling summaries of RTR analyses applied in regulatory activities, etc. Little discussion on comparing of screening model output to field data. This discussion needs to be added to the body of the report, or these paragraphs dropped from the executive summary.

Page 3, line 25-27 – Conclusion of “reasonable and logical” whereas EPA questions are about appropriateness of methods.

Page 3, lines 33-41 – These ideas do not have corresponding discussion in the body of the report.

Page 5, lines 9-12 – This refers to Question 4. Expected to see statement - “The SAB found the methods used for evaluations of lake, plume rise and time series data appropriate but in need of further refinement.” Why is summary of Q4 after summary for Q5?

Page 5, line 14 – “The SAB found the methodology for”

Alignment and consistency of Letter to Administrator:

I don't support using the current Letter. I find it does not appropriately represent the panel findings and recommendations. It expends too much landscape on issues such as operational effectiveness, probabilistic analysis, and sensitivity analysis and not enough on the panel findings of appropriateness or inappropriateness of the RTR methodology components – the issues it was asked to address.

Page 2, line 5 – A finding of “reasonable” versus “appropriate”.

Page 2, line 6 – “SAB notes...” use “The SAB concludes ...”

Page 2, line 10 – “SAB suggests...” use “SAB recommends”

Page 2, lines 10-16 – Coming where this does in the letter, it seems this should be a key finding of the panel. But reading the report, I find this “conclusion” is really not a “finding” at all but more like a suggestion that shows up in two question discussions. I recommend the probabilistic approach not be mentioned in the Letter. The recommendation for further sensitivity analysis finds more discussion in the body of the report and hence could be mentioned in the Letter, but possibly toward the end.

The second to last paragraph [page 2, lines 34 to page 3 line 7 is more in line with what I would expect to see in the Letter. It lays out what “The SAB finds....” in clear language.

Somewhere in the Letter, mention should be made to ALL issues the SAB was asked to address.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

With some difficulty it is possible to identify support for all conclusions and most recommendations. Deficits in such support are identified in the detailed discussion in section 1 above.

Comments from Dr. Tara Sabo-Atwood

Overall, the Draft SAB report is well-written, comprehensive and generally responds clearly to the 8 charge questions posed by the EPA. There are a few points of clarity that are highlighted below for select charge questions.

1. Were the charge questions to the committee adequately addressed?

The charge questions were all addressed and most of them quite thoroughly. There are several questions where additional clarity could be imposed as noted below.

Charge Question 13.1, Pages 10-11: The response regarding the need for assessing screening efficacy is sound and well justified. Two ways to address or improve screening efficacy of the tiered approach are proposed. The first calls for reviewing the number of facilities screened out by each tier. While not included in the initial report, data obtained by the committee was presented that captured the following “Tier 1 on average screened out 30% of affected facilities and tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively, of affected facilities”. It is mentioned that this information was obtained for the five most recent RTR analysis. The timing that this period covers is not apparent beyond mentioning that data was included from the previous 5 RTR reviews. Without defining the years spanned and whether the same screening approaches were utilized across this time period makes the averages difficult to interpret. There should be added clarity surrounding what defines an RTR that uses the current approach to screening and whether minor adjustments need to be considered to include such data in the assessment. The second approach to assessing screening efficacy proposed is validation or ‘ground truthing’ of the 3 tiered approach. Another valid point, yet the acceptable types of monitoring data that should be utilized for such purposes is not well defined and could be further clarified.

Charge Question 13.1, Page 12: There is reference to the need to limit RTR input data errors and a suggestion that EPA could further develop and expand its affirmative efforts to ensure RTR input data accuracy. However, there is no explanation as to whether there is a major data input problem and a specific need to modify current practices. I am sure there are areas to improve upon but if the report is going to broach this issue then it would help to have a stronger justification and proposed solutions. For example – are there certain aspects of data input that are more prone to errors and if so can some solutions be proposed? It is not clear if current input data quality assessments are being implemented routinely and whether such data are currently available. The report also refers to possible approaches being discussed to reduce such errors from a previous public meeting (EPA 2018b) but I could not find these beyond mention that the topic of data errors were discussed.

Charge Question 13.1, Page 13: The additional comment regarding the underestimation of cancer risk for ‘early life exposures’ related to breastfeeding is an excellent point to emphasize. The report refers to the mutagenic mode of benzo(a)pyrene and that MIRC includes age-specific factors to account for the mutagen’s higher potency during childhood. It is further stated that cancer potency for BaP is assumed 10-fold greater for the first 2 years of life and 3-fold greater for the next 14 years and these factors were incorporated into a time-weighted total increase in potency over a lifetime of 70 20 years. However, the current RTR report does not seem to include breastfeeding in the early life exposures. There are several studies to support the detection of significant levels of low and high molecular weight PAHs, including BaP, in breastmilk, that are reported to be higher than the permissible limit of $1 \mu\text{g kg}^{-1}$ (1). There is variability in the few studies reported, highlighting the need for more work in this area to best direct inclusion of breastfeeding as a significant route of exposure. Perhaps this comment could

be expanded to include references to highlight its importance as and need for more information.

1. Santonicola S, De Felice A, Cobellis L, Passariello N, Peluso A, Murru N, Ferrante MC, Mercogliano R. [Comparative study on the occurrence of polycyclic aromatic hydrocarbons in breast milk and infant formula and risk assessment](#). Chemosphere. 2017 May;175:383-390.
2. Cok I, Donmez MK, Uner M, Demirkaya E, Henkelmann B, Shen H, Kotalik J, Schramm KW. [Polychlorinated dibenzo-p-dioxins, dibenzofurans and polychlorinated biphenyls levels in human breast milk from different regions of Turkey](#). Chemosphere. 2009 Sep;76(11)

Charge Question 13.1, Page 14: The last comment in this section refers to a limitation of the chemical-by-chemical analysis approach for the industrial category whereby cumulative effects and chemical interactions from emissions emitted from nearby alternate sources would be missed. This could lead to an underestimation of health risk by not considering the cumulative risk using the current RTR method. This is an excellent point, yet the level of importance of this statement does not come across. Is the approach significantly flawed, should it be significantly changed or modified, and if so, how?

Charge Question 4, Page 20: Hour-by-hour data from the closest meteorological station may not reflect microclimate conditions (topography, directional valley orientations, inversion conditions). It is suggested that local conditions be used, however it is not clear whether local conditions should be the sole data source OR that conditions can be garnered from meteorological stations that are within a given well-defined distance/proximity and therefore both data sources are acceptable under certain conditions. Also, is there a select database that should be the primary source for gathering such data? This could be further clarified.

Charge Question 6, Page 24: It is stated that selenium be included as a chemical to screen due to its importance in ecological impacts. Additional justification with references should be added to strengthen the support for its inclusion and to better define 'ecological impacts' and their relevance to the assessment.

Charge Question 7, Page 27: In the discussion of alternate utility of NLCD, it is suggested that class 22 (low intensity developed) be used as an 'urban' identifier, defined as 20%-44% impervious surfaces. An alternative approach is to use percent impervious surface data layer produced for each NLCD generation as a measure of net change in imperviousness between NLDC generations. It is not clear if one or both of these should be used. Can these approaches be prioritized?

2. Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

I do not see any technical errors or omissions based on my area of expertise.

3. Is the draft report clear and logical?

Overall, yes.

One point to note is that the distinction between a ‘recommendation’ versus ‘comment’ is not always clear. For example, under charge question 1, there seem to be several recommendations/suggestions written in paragraph form in pages 11-12. Then there are additional comments and recommendations listed in bullet form on pages 12-14. Is there a weighted difference in these recommendations – i.e. major vs. minor? I noticed that several of the latter points are not necessarily captured in the executive summary. Perhaps summarizing what the major recommendations are for more complex charge questions would provide clarity.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes, in general. Several conclusions and recommendations could be further clarified as stated above.

Minor Comments

- P15, Lines 18-20: “The REF methodology consists of two read-across approaches - one to handle toxicology data gaps and the other to handle information gaps regarding environmental transport and fate”. What defined ‘toxicology’ here is not clear – focused solely on human health effects, TEF values?
- P18, Lines 20-21: This sentence is missing something – “and it is available by stream segment. The Office of Pollution....”

Comments from other SAB Members

Comments from Dr. Deborah Hall Bennett

1. Were the charge questions clearly addressed?

On charge question 8, I felt that more specific recommendations could have been provided for locating populations within a census block. While I agreed with the general guidance provided by the SAB, I felt it may be more helpful to provide some specific examples of how the EPA might locating the population more exact. For example, they could use the fence line of the facility and location of nearest downwind residents as specific points of reference. When noting the risk assessor should provide “sufficient information” to reproduce the selection they could provide some examples, or suggest the locations be specified.

2. Are there any technical errors or omissions?

On page 16, the SAB expressed concern regarding the sole use of Kow to predict exposures, a concern I share. The report provided two suggested options. I considered a third option that was not mentioned that may or may not be applicable. QSAR techniques for estimating chemical properties continue to be further developed, and I wonder if using these types of estimates for the needed half-lives of the chemicals could be considered as a third alternative to improve estimates.

On page 18, the SAB encourages the EPA to find more realistic assumptions for fisherman, suggesting the use of the NHANES data. My concern is that if my understanding is correct, that this pathway is to

estimate a low-income person who supplements their protein intake with fish, rather than a nationwide survey, it may be more appropriate to find a survey of fish consumption focused on this population.

3. Is the draft report clear and logical?

On page 3, lines 18-23, the report discusses how field measurements should be compared to model estimates in a Tier 3 evaluation. In this section, the complication that many of these compounds result from multiple source categories, making such a comparison possibly difficult, is not mentioned. This idea is somewhat eluded to in the more detailed report, but should be presented more clearly.

Page 5, line 1, the report introduces the gardener scenario. Having an interest in dermal exposure, my mind immediately went toward an individual who provided gardening services to homes, and had significant daily contact with dirt. I later learned this scenario was someone raising crops in their backyard garden. The term “gardener” should be defined here.

4. The conclusions were supported by the body of the report.

Comments from Dr. Robert Blanz

Charge Question 1: Does the 3-tiered multipathway approach appropriately eliminate from further consideration those low risk facilities?

The report says it’s reasonable and logical and has the potential to achieve EPA goals but the overall effectiveness is not clear (lines 30-38, page 10). It appears from the response that the SAB does not believe the approach appropriately eliminates low risk facilities.

Charge Question 2: Does the REF methodology account for differences in fate and transport among POM and dioxin congeners?

SAB finds that the read-across extrapolation should be refined (page 16, line 10-11) and that the key parameter inputs are not adequately described (page 16, line 23-24) and that a full review is precluded (page 16, line 28) by the absence of examples of dynamic EEF changes. It appears from the response that additional research is needed to generate the regression slope (Kow and LADD) and evaluate the underlying fate and transport parameters.

Charge Question 3: Does the SAB find that 1.) The assumptions about fisherman behavior; 2.) The assumptions for PB-HAP deposition; and 3.) The assumptions on fisheries sustainability are appropriate?

The response does list some of the assumptions and parameters used to evaluate a fishing scenario. SAB finds many of these assumptions are too conservative to achieve the objective of a screening level risk assessment. EPA is advised to consider more realistic assumptions and parameters to achieve the objective.

The Report appears to find that the SAB is OK with the way the fishermen and women behave (page 17 line 22-23) but has an issue with what they are catching (beginning on line 43). Lastly, SAB doesn’t have much to say about fisheries sustainability other than fisheries biomass is variable.

It appears that SAB is not particularly enamored with the use of the dispersion model used and it needs more documentation (page 18, line 36).

Charge Question 4: Does the SAB find that the methods used for evaluations of 1.) Lake data; 2.) Plume rise; and 3.) Time series meteorology and plume rise are appropriate?

The response is inconclusive as it does not appear to address the lake data and plume rise or finds that it is not justified. It recommends that the Lake data should be automated to be reproducible (page 19, line 30-41), but provides little guidance on how to approach it. The report finds that the plume rise model should be AERMOD.

It appears from the response that the SAB does not consider these methods appropriate.

Charge Question 5: Does the SAB believe the addition of and approaches for the gardener scenario are appropriate and improve the ability to characterize ingestion risks?

The report seems to indicate that the SAB, with a few technical reservations, agrees the gardener is a good addition but needs to be separated from the farmer scenario.

Charge Question 6: How about the environmental risk screening approach and that the pollutants, ecological endpoints, and benchmarks are appropriate?

The report appears to indicate that the overall methodology and recent revisions are appropriate but EPA should have included selenium, updated mercury and chloride loading, and used AERMOD for modeling.

Charge Question 7: This refers to the Urban/Rural Dispersion Selection Enhancement Tool.

The review report states a preference for the land use procedures over the population based census approach but otherwise appears to be OK with the approach.

Charge Question 8: This charge question is about the use of the Census Block Receptor Check Tool.

It seems that SAB doesn't favor the use of this Tool and appears to include I told you so in the 2009 review.

Questions before the quality Review

1. "Were the charge questions adequately addressed"?

My response is maybe on Charge Questions 5, 6, 7, and 8 but only vaguely on the first 4.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

See responses to Charge Questions 1-4 for issues that, in my opinion, are not adequately dealt with.

3. Is the draft report clear and logical?

Clear, yes

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

I did not detect any conclusions but the recommendations seem to be germane to the text.

Comments from Dr. Todd Brewer

1. Yes, I believe that the charge questions, in relation to all 8 topics, were adequately addressed.
2. No, I did not see any technical errors or omissions during my review of the draft report.
3. Yes, the draft report is well-written, clearly articulated, and logical to follow.
4. Yes, I believe that the conclusions drawn and/or recommendations made by the SAB working group are supported by the body of the draft report.

Also, in keeping with the direction to comment on the alignment and consistency of the message given in the Letter to the Administrator, the Executive Summary, and the body of the report, I would say that all 3 portions of the document are aligned in message and consistent in the discussion and presentation of recommendations related to the charge questions considered regarding the eight topics focused on within the Agency's draft RTR methods document.

Comments from Dr. Alison C. Cullen

1. Were the charge questions adequately addressed?
Yes, the charge questions were adequately addressed.
2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?
I am not aware of technical errors in the report or incompletely addressed issues.
3. Is the draft report clear and logical?
The draft report is clear, logical, and very well organized.
4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?
Yes.

Comments from Dr. Otto Doering

1. Were the charge questions adequately addressed?
Yes, they were.

2. Are there any technical errors or omissions in the report or issues that are not adequately

dealt with in the draft report?

I did not find any.

3. Is the draft report clear and logical

Yes.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report

Yes.

My impression is that this review report is well done. And the suggestions made are constructive and well founded.

Comments from Dr. Susan Felter

1. Were the charge questions to the committee adequately addressed?

Yes

2. Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

None that I am aware of.

3. Is the draft report clear and logical?

Overall yes. Following are a few questions that might lead to minor edits:

- It seems from bottom of p. 5 that by Tier 2, 90 – 100 % of facilities are screened out (am I reading this right)? This means that only a small fraction would go to Tier 3 – and would anything be left out that is not screened out? This seems a bit at odds with these being screening tools that also identify “those facilities where a refined multipathway or environmental risk assessment may be needed.”

58 In summary, the SAB supports the framework and direction of refinements EPA has been
39 making to the screening methodology for the residual risk portion of RTR analyses. By the
40 EPA’s accounting, provided in response to inquiry by the SAB, for the five most recent
41 RTR analyses conducted, Tier 1 on average screened out 30% of the affected facilities, and
42 the Tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively,
43 of the affected facilities. This demonstrates a commitment to effectively manage EPA

Related to this, the SAB recommends that EPA consider using probabilistic analyses (vs point estimates). While this certainly offers an opportunity to refine the assessment, I question whether it’s appropriate for an initial screen (because of resources needed). Later in the document, the SAB does say that probabilistic analyses could be done “perhaps initially through case studies on Tiers 2 and 3”. Given the apparent high percent of facilities that are screened out already at Tier 1 and Tier 2, the value of adding probabilistic analyses is not clear – perhaps this should be suggested as an additional refinement at Tier 3 (only), if needed?

- On the topic of TEFs for carcinogenic potency, the SAB raises a (good) question about the use of TEFs for noncarcinogenic PAHs. The language is very soft (p. 4: “The SAB also

finds the REF method would greatly benefit from better explanation, documentation and statistical analysis in terms of: (a) documentation of TEFs, including consideration of whether assigning a TEF for carcinogenic activity is appropriate for certain PAHs not traditionally considered as carcinogens”). I suggest strengthening the language (also elsewhere in the report) specifically regarding the PAHs that are not considered to be carcinogens. Rather than suggesting that the EPA needs ‘better explanation/consideration’, I think the SAB should make a clear statement that TEFs for cancer potency should not be applied to PAHs that do not raise a cancer hazard and that the Agency should remove those PAHs from the TEF calculations or provide a justification why they are included.

- Regarding the following text on p.5: “The SAB finds that insufficient information was provided about the census block receptor check tool, especially regarding criteria used to determine the number and placement of new receptors. The SAB is concerned that the process would not be reproducible if another risk assessor were to subsequently model a facility.”

- It’s not clear if the SAB has a concern that the process would not be reproducible or if there is insufficient information for the SAB to make this determination. I also wonder whether the language should be tweaked – is the concern really that it is reproducible, or is the concern that it is sufficiently representative (recognizing that the two are linked)?

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Overall yes

Minor editorial:

Cover letter and throughout: Text refers to “the risks remaining” – suggest adding the word “potential” before risks as it should not be assumed that risks will remain after application of MACT. If this language is also in the EPA report, the SAB might consider making this recommendation to the EPA as well. The screening methods are assessing low-level *exposures* (which may or may not be associated with risks) that remain after application of the MACT.

Comments from Dr. John Graham

In general, I am quite impressed with the draft SAB contribution and my comments are mainly intended to help clarify and sharpen SAB’s message on a few points.

Executive Summary

p.10, 18-23 SAB calls for some “ground truthing” by comparing field measurement data (e.g., re: deposition) with the predictions from the screening exercises. It might be useful to clarify in the text (not necessarily in the ES) what EPA might be expected to do after the ground truthing is conducted. For example, if the measured deposition values are in fact larger than the screening predictions, then the desired conservatism has not been accomplished and adjustments to screening procedures may be appropriate. On the other hand, if measured deposition values are vastly lower than predictions, then the screening methods may be overly conservative, calling for

refinements to reduce conservatism in the future. The related language in the text moves in this direction but the guidance could be sharpened.

p. 11, 1-6, and corresponding text on p. 12, 9-17 and pp. 23-24, 16-21, 23.

At various points in the draft document, “probabilistic analysis” is recommended for consideration. It was not entirely clear to me what kind of analysis was envisioned (uncertainty analysis only or also variability analysis) or how the agency might utilize the probabilistic analysis. Nor was it clear whether the probability analysis would apply only to exposure or also to toxicity. A probabilistic analysis in a screening context may need to be designed and/or considered differently than a probabilistic analysis of risk in a final rulemaking context but this kind of distinction is not mentioned in the draft. A statement is made on p. 12 that probabilistic analysis contributes to accuracy but, in the most basic sense, the probabilistic analysis of uncertainty simply portrays the extent of the unknowns. It does not contribute to accuracy per se (unless it motivates additional data collection and uncertainty reduction). P. 12 awkwardly refers to whether “data” might be available to inform the probabilistic analysis but, insofar as the relevant data are available, it would seem that probabilistic analysis might not be necessary. Thus, my underlying concern – as a big supporter of probabilistic analysis – is that our encouragement of probabilistic analysis does not have enough specificity or nuance to supply the Agency with a practical direction in this particular screening application.

Text

p. 10, line 36

in addition to saving EPA resources, some resources in the regulated community may also be saved.

p. 19, lines 19-32

data quality is costly to enhance, and virtually all data has some degree of error. Our unqualified endorsement of high quality data should be nuanced with an appreciation of the cost of improving data quality, especially since we are discussing data used in screening (rather than final) risk assessments. Of course, if data quality improvements have little cost, they should be implemented.

p. 21, 28-33

the discussion of cumulative risk, where risks of the targeted facilities might be added to the risks of the same chemicals from nontarget facilities/sources, seems to assume that the benchmark of acceptability would be the same in either case. However, the benchmarks envisioned by policymakers may have been articulated with only the targeted facilities in mind. Stated differently, the benchmark of acceptability might be more permissive if all sources of exposure to a chemical in a person’s life are included in the calculation than if only exposures from a narrow set of facilities in an industrial subcategory are considered. Thus, SAB and the Agency need to appreciate that the concepts of cumulative risk and benchmark of acceptability

may not be entirely independent of each other (unless a strict dose-response threshold is known with certainty and is uniform across the exposed population). The current drafting seems to imply that they are independent. My concerns could be addressed by adding a sentence of two of context or simply deleting this weakly-developed point about cumulative risk including nontargeted facilities.

Comments from Dr. Michael Honeycutt

1) Were the charge questions adequately addressed?

Yes, the charge questions were adequately addressed.

2) Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

I did not see any discussion of the facility-specific selection of contaminants and estimation of emission rates for use in the screening methodology, though it could have been addressed in another guidance document. I'm wondering if contaminant selection will be based on process knowledge or some sort of (e.g. stack) testing? If it's based on stack testing, how will non-detects be handled in the screening methodology? Facility-specific emission rates can vary from year to year, depending on the type of facility. Will the screening method use the permitted emission rate? The estimated maximum actual (as opposed to permitted) annual emission rate? The average actual emission rate estimated over the lifetime of the facility?

3) Is the draft report clear and logical?

Yes, the draft report is clear and logical.

4) Are the conclusions drawn, or recommendations provided, supported by the body of the draft report?

Yes, the conclusions and recommendations are supported by the draft report.

Comments from Dr. Merlin R. Lindstrom

1) The responses not only adequately addressed the questions, but they also contained suggested improvements to the proposed Screening Methodologies.

2) I found no technical errors or omissions. The report is well written.

3) Yes, the draft is clear, logical and easy to follow.

4) Yes, the conclusions and recommendations are supported by the body of the draft report.

Comments from Dr. Kristina D. Mena

1) Were the charge questions to the committee adequately addressed?

Yes

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Letter to Administrator Pruitt:

page 2, line 3 extra “and”

page 2, line 27 include (LADD) after “lifetime average dose estimates”

Executive Summary:

page 2, paragraph 3 This paragraph includes comments that the charge questions to the SAB do not address the screening methods from a technology aspect. Do the SAB reviewers think it would have been important to include such charge questions?

page 2, line 30 Was the face-to-face meeting in June or July? In the letter to Administrator Pruitt, July 29-30, 2017 is given as the date but here it indicates June 29-30, 2017.

page 3, lines 5-7 Perhaps explain this recommendation.

page 3, lines 38-39 How can EPA “further develop and expand its affirmative efforts to ensure RTR input data accuracy”? Could recommendations be provided here?

page 6, line 5 Missing period at end of sentence.

Introduction

page 9, lines 25-26 The SAB did not address the impacts to regulation because that aspect was not part of the charge questions, correct? Could the questions that ask about the appropriateness of a method be answered from a regulatory perspective?

Response to Individual Charge Questions

page 10, lines 41-43 Although recommendations are given later in the draft report, should the statement “. . . operational effectiveness could be evaluated by reviewing the number of facilities screened out by each tier” include the issue of possibly screening out high-risk facilities?

page 11, paragraph 2 There is no end parenthesis in the paragraph.

page 13, lines 14-17 What about food consumption data available from the United States Department of Agriculture Economic Research Service? These data could be used to inform risk assessments.

page 17, lines 26-29 Does the SAB think the conservative assumptions should remain but include a range of defined parameters so that perhaps more realistic exposures are estimated? Or, is the SAB recommending to reconsider these “too conservative” assumptions and replace them with improved defined exposure parameters that may better inform risk screening? Is there enough information in this draft report to guide EPA on “better” assumptions? As explained on page 19, line 6, conducting a sensitivity analysis of the defined parameter distributions is important.

page 22, lines 36-38 Given the context of the paragraph, what is the recommendation to the EPA?

3) Is the draft report clear and logical?

Yes - However, the response to Charge Question #1 on page 10, lines 36-38 should perhaps be summarized/emphasized at the end of this section so that this overall conclusion by the SAB is understood (i.e., why does the approach only have “potential” and what could be done to clarify and/or improve its effectiveness?).

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes

Comments from Dr. Larry Monroe

1) Were the charge questions to the committee adequately addressed?

Yes, all in all I agree that the draft adequately addresses the charge questions.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Although I agree with most conclusions, there are two that I would suggest need strengthened.

First, on Page 11, Lines 11 through 18, the draft report suggests “ground-truth”-ing the evaluation by comparisons to actual data from sites. I see this as an absolute requirement to allow the Agency to use the method with confidence. Having spent many years trying to understand transport, deposition, transformations of mercury, I know that the models often miss important details of the actual physical actions.

Second, also on Page 11, Lines 33 through 40, discusses how the use of multiple high-end health protection parameters can give an overestimation of risk. This issue could make the entire tiered screening exercise a defacto decision to include all sources and thus defeat the purpose of the exercise. This is obviously a complex area, but would need to be addressed in this and other actions by the Agency. Perhaps the suggestion on Page 12 to move towards a probabilistic approach using median values and observing the effect of multiple low-likely events could help solve this issue. The report does note the difficulty in constructing the distributions necessary with available data.

Additionally, on Page 16, Lines 2 through 8, the report discusses the considerable variability around the regression for using to estimate the EEF. I would question the quote in the draft report:

The variability around the regression line is up to two orders of 6 magnitude and thus the calculated EEF may substantially underestimate the LADD for 7 some undefined members of

data-poor chemical classes.

While it is true that the calculated EEF may underestimate the LADD, is it not as likely that it will overestimate the LADD. I suggest the text needs to be changed if this is true.

3) Is the draft report clear and logical?

Yes, I commend the authors for their ability to convey the material in a very readable document.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

In general, I agree that the conclusions and/or recommendations are supported by the body of the draft report.

Comments from Dr. Thomas Parkerton

1. Were the charge questions adequately addressed?

Yes, the eight charge questions posed have been systematically addressed in the draft SAB report.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

Based on the review of the draft EPA RTR screening methodologies report, there are a number of concerns identified that were not specifically captured in the draft SAB review that warrant further consideration by the SAB panel.

Response to Charge Question 1.

No justification is provided for using the 90th percentile for ingestion of farmed foods (farmer scenario) while the 99th percentile is applied for fish ingestion (fisher scenario).

Response to Charge Question 2.

The proposed REF methodology requires that exposure equivalency factors (EEFs) be derived for POM and Dioxin/Furan (D/F) congeners. EEFs represent the predicted ratio of human intake (obtained using TRIM.Fate and Multimedia Ingestion Risk Calculator) to a given congener to a reference substance (either BaP or TCDD) assuming the same air emission rate. In principle, EEFs need to be derived separately for fisher and farmer exposure scenarios. However, the same

value derived in Tier I (which reflects both exposure scenarios) are applied to the two individual exposure scenario in Tiers II and III without justification.

A second concern relates to the transparency and adequacy of the model parameters used for multimedia human exposure assessment. In the case of D/F congeners, it is stated sufficient congener-specific data were available for model application. In the case of POM, EPA indicates that sufficient input data were only available for a limited number of congeners so that EEF was estimated using an empirically derived relationship with Log octanol-water partition coefficient (Kow) for a subset of substances. The draft SAB review correctly highlights concerns that Kow is an imperfect predictor of human exposure (pg. 15).

In addition, EPA does not explain assumptions used for parameterizing D/F or POM substance-specific bioaccumulation factors that are used in the estimation of EEFs. These parameters serve as key inputs for translating modeled exposures in air, water and soil into farmed food and fish concentrations. More specifically, it is unclear if biotransformation, which is well known to confound simple Kow-relationships for estimating bioaccumulation potential, has even been considered. The importance of this process in modulating fish bioaccumulation factors can be quantitatively accounted for by using the BCFBAF model that is included in EPA's EPISuite software (<https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>). Further, in the case of PAHs, in-vitro studies published by USEPA (Nichols et al. 2013; Fay et al. 2017) indicate that the fish biotransformation rate increases with substance hydrophobicity (i.e. Kow). Thus, the technical basis for the assumed positive relationship between EEFs with Kow seems questionable at least for the fish ingestion pathway. Similarly, it is uncertain if recent literature has been considered for model parameterization of plant-related bioaccumulation parameters (Shunthirasingham et al. 2017).

It is recommended that EPA use relevant models/literature to define substance-specific bioaccumulation model input parameters for D/F and POM substances and document the parameters selected to improve the technical basis and transparency of proposed EEF values implemented in the RTR screening methodology. While assumptions related to the bioaccumulation of arsenic in fish have been provided in Appendix B.7, bioaccumulation parameters used for cadmium and mercury are not reported and should be clearly documented based on up to date and reliable data.

Response to Charge Question 6

EcoEEF values for D/F and POM congeners are required for surface water, soil, sediment and wildlife receptors but are not provided or adequately explained. The same concerns regarding model parameterization of substance-specific bioaccumulation parameters identified in response to question 2 is also applicable to EcoEEF values derived for piscivorous and terrestrial wildlife receptors.

For derivation of ecoTEF for POM substances, water and sediment quality benchmarks published by USEPA (Burgess et al. 2013) would appear to provide an improved mechanistic

basis to support derivation of ecoTEFs. In fact this reference could be cited in support of the last bullet in this section on page 25 line 23.

For the 5 substances for which Tier I health screening threshold emission estimates have been developed (Table 3-3 in the EPA report), values are lower than corresponding environmental screening emission estimates across all assessment endpoints calculated (Table B-21 in the EPA report). Thus, risk screening estimates for human health appear to provide adequate protection for ecological effect endpoints. In such cases, this raises the question regarding the need for further environmental risk screening for these substances. It would seem logical to recommend that EPA provide additional discussion regarding the relative magnitude of estimated tier I emission screening values obtained for human health versus environmental risk and practical implications for RTR reviews.

3. Is the draft report clear and logical?

The report is generally clear and logical. Several editorial comments are provided for consideration to improve or clarify the draft text.

In the executive summary on page 2, suggest clarifying the second sentence in the third paragraph. A proposed change to the text is:

“While limited data were subsequently provided by EPA to allow a preliminary evaluation that helped SAB better understand the screening efficacy of the proposed methodology further data and analyses are needed to enable conclusions to be drawn.”

In the next paragraph and in the body of the report, the authors indicate that read-across extrapolation of environmental fate “could” be refined. Given the technical concerns raised regarding this approach, it seem that a more accurate consensus recommendation is that this approach “should” be refined.

On page 4, line 23 suggest replacing “*traditionally considered*” to “*currently identified*”

On page 5, line 19 sentence structure is awkward please revise.

On page 5, line 36 suggest deleting “*so as to be reproducible by independent expert analysts*” as this text seems superfluous.

On page 5, line 43 suggest revising “*This preliminary analysis indicates the proposed methodology can assist EPA in effectively managing...*”

On page 6 is last sentence of paragraph needed?

On page 18, line 11 fix typo and line 22 suggest replacing “However,” with “Alternatively,”

On page 22 line 28-29 the text states that farmer-specific rates are less health protective. However, in the previous sentence it states that this scenario includes exposure pathways

associated with run-off (from agriculture) which would make this scenario more, not less, health protective than the proposed urban scenario proposed by EPA which excludes this term. If this sentence is deleted the text makes more sense as the key point seems to be that the urban scenario should consider potential runoff related exposures.

The text on page 22 lines 34-39 is confusing. The paragraph begins by stating the assumptions are not unreasonable (i.e. are reasonable). The authors then indicate that the assumptions may in fact be too conservative. The paragraph then concludes that EPA should consider alternative and higher soil intake rates for the adult gardener (presumably adding further conservatism). Please revise to address these inconsistent messages.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

The conclusions and recommendations provided in the draft SAB report appear to be adequately supported. However, I have concerns regarding one recommendation and one conclusion that is provided as detailed below.

In both the executive summary and the main body of the draft SAB report (pg. 2 and 16), the SAB suggests that two approaches be considered to revise the EEF vs Kow relationship that is illustrated in Figure 3-2 of the EPA report. This recommendation assumes that it is not possible to develop substance-specific EEFs for the “data poor” substances identified by EPA. However, given the availability of quantitative structure property relationships to estimate fate properties for the various congeners in this substance class for which data are not available, it would seem feasible to directly derive substance EEFs without the need to further improve an empirically derived EEF correlation with Log Kow. I believe this approach better reflects the state of science in exposure assessment modeling and would avoid over simplifying estimates of multimedia exposure based only on Kow using a limited number of “data rich” substances that may not adequately represent the fate properties of the modeled substances. Thus, I recommend this approach be proposed as an alternate to draft recommendation currently provided. For transparency, EPA should describe the substance-specific fate property estimates used in deriving all EEF values. This later point builds on the recommendation in the current SAB draft report that additional documentation describing the methods used for EEF derivation is needed not only for human health risk (page 4, line 33) but also for environmental risk screening.

The SAB concludes that the expansion of ecological assessment endpoints are reasonable and that the benchmarks, and the use of a tier system, are justified. While the assessment endpoints and tiered framework appear logical, EPA applied a hierarchy of preferred benchmark sources to enable selection of benchmarks for each environmental HAP for each ecological assessment endpoint. The technical justification of this approach is questionable. Many of the preferred benchmarks are quite outdated (often derived from studies performed in the 1980s - 1990s as highlighted by the SAB on page 24 of the draft review). Further, use of various benchmarks derived under different programs or agencies provides an inconsistent evaluation of the underlying hazard data (i.e. use of different application factors) for the purpose of benchmark

derivation. In addition, both causal and association-based benchmarks were indiscriminately included in the selection process. For example, some benchmarks are based on field studies that are derived from simple correlations to observed effects (i.e. sediment toxicity or benthic community metrics). Such quality benchmarks are based on association and not causation and thus appear to provide an inappropriate technical basis for substance-specific risk screening in the context of objective RTRs. Another issue is that the reliability of the underlying hazard data used to establish the benchmark is not transparent or critically assessed for reliability as highlighted by the SAB (page 24).

Given that these benchmarks are fundamental to the derivation of screening emission values further scrutiny of these values is needed. For a number of the substances targeted in the RTR methodology, reliable hazard data are available to support a consistent, statistically based derivation of causal, substance-specific benchmarks for the various ecological assessment endpoints using species sensitivity distributions. For water and sediment quality endpoints, a recent review that includes several substances included in the RTR evaluation have already been published by EPA (Burgess et al. 2013). For other endpoints, recent literature reviews should be considered so that the substance-specific benchmarks adopted have a clear technical, and ideally, mechanistic basis that is up to date with the available hazard information and current state of the science (Korsman et al. 2016; Fuchsman et al. 2017; Sample 2017).

In addition to the above concerns, a few of the general statements made could be strengthened by supporting references (or revised accordingly).

On page 22 line 7 it is stated that many gardeners also keep egg-laying chickens. Suggest revising to be more objective unless there are data to support this claim.

On page 26 line 35-37 it is stated that the land use procedure finds fewer urban areas than the HEM default procedure, indicating the latter misclassified turbulence in some cases. What is the basis for making this conclusion?

Citations:

Burgess, R. M., Berry, W. J., Mount, D. R., & Di Toro, D. M. (2013). Mechanistic sediment quality guidelines based on contaminant bioavailability: Equilibrium partitioning sediment benchmarks. *Environmental Toxicology and Chemistry*, 32(1), 102-114.

Fay, KA, Fitzsimmons, PN.; Hoffman, AD; Nichols, JW (2017). Comparison of trout hepatocytes and liver S9 fractions as in vitro models for predicting hepatic clearance in fish, *Environmental Toxicology and Chemistry* 36(2):463-471

Fuchsman, P, Brown, LE, Henning, MH, Bock, MJ, Magar, VS. (2017). Toxicity reference values for methylmercury effects on avian reproduction: Critical review and analysis. *Environmental Toxicology and Chemistry* 36(2):294-319.

Korsman, JC, Schipper, AM, Hendriks, AJ. (2016). Dietary Toxicity Thresholds and Ecological Risks for Birds and Mammals Based on Species Sensitivity Distributions, *Environ. Sci. Technol.* 50: 10644–10652.

Nichols, JW, Hoffman, AD.; ter Laak, TL; Fitzsimmons, PN. (2013). Hepatic clearance of 6 polycyclic aromatic hydrocarbons by isolated perfused trout livers: prediction from in vitro clearance by liver S9 fractions. *Toxicological Sciences* 136(2):359-372.

Sample, BE (2017). An evaluation of inorganic toxicity reference values for use in assessing hazards to American robins (*Turdus migratorius*), *Integrated Environmental Assessment and Management* 13(2):352-359.

Shunthirasingham, C; Dettenmaier, EM.; Zaleski, RT; Fantke, P (2017). A review of measured bioaccumulation data on terrestrial plants for organic chemicals: Metrics, variability, and the need for standardized measurement protocols. *Environmental Toxicology and Chemistry* 37(1):21-33.

Comments from Dr. Robert Phalen

Four quality review questions. My answer is , "yes" for all except question 2. When we are given charge questions, they do not allow for additional relevant comments. Examples include 1. whether or not the EPA approach here is cumbersome (e.g., Should environmental sampling alone replace the modeling approach?); 2. Should adverse health-related trade-offs be included (e.g., Reducing selenium levels can result in decreasing dietary intakes below the required minimum daily intakes.); and 3. As the data are used for risk assessments, should the risk assessment be on the overall risks associated with alternate "decisions" about the chemical, instead of isolated information on the potential toxicology of the chemical.

This one-sided approach can increase overall adverse health effects in several ways, such as inhibiting the availability of goods and services that are life-sustaining. It would be good to always add another charge question such as, "Does the SAB have any additional comments about the report?"

RE: The Draft letter to the EPA Administrator.

1. pg. 1, line 29, The phrase "consensus advice" concerns me because scientists nearly always disagree on some points in a report. Would it be better to drop "consensus", to leave room for minority viewpoints, should they arise? In that case, the letter could add minority opinions, if any, attached as an Appendix so the Administrator could be fully informed. Not including minority opinions in official reports (and other communications) seems to be a relatively recent development.

2. pg. 2, line 8. From a "public health point of view" does not include adverse health trade-offs, so that might be stated here. I recall that Southern California nearly lost the dairy industry because air quality concerns required them to cover the manure to reduce ammonia emissions, but ground water concerns required them to spread the manure out on the ground to off-gas. They could not comply with both directives.

3. pg. 2, line 20. "Data" is plural in scientific documents (datum is the singular), so "data was" should be replaced by "data were".

RTR Panel Draft Report.

pg. 3, line 22. The phrase "ground truth" has different meanings. Here it seems to mean "field data". It should be defined or replaced with the specific meaning. Also given the errors inherent experimental data, "truth" implies more faith than might be warranted.

4. pg. 4, line 41. Could an altitude for "upper-air wind speeds" be given? In meteorology, it might imply extremely high (jet stream) altitudes. Also "speeds" might be changed to "velocities" because wind direction is also important in dispersion modeling.

5. pg. 5, line 17. As selenium deficiency is implicated in poor crop yields and in several human diseases (including cancer), change "it be added" to "it be considered".

6. pg. 11, line 12. See comments on "ground truth" for pg. 2 above.

7. pg 18, line 3. What does "pan fish" mean? Is it a type of fish or a cooking method?

8. pg. 20, lines 9-10. See comments for pg. 4 on "wind speeds".

9. pg. 22, lines 7-32. My impressions are that this expands the modeling difficulty considerably, and that the payoff might not be worth the effort.

10. pg 24, line 3. See comments on selenium for pg. 5 above.

11. pg. 24, line 32-33. The Klimisch score has been criticized because of its GLP bias, and other limitations, as I'm sure EPA knows. Perhaps the sentence could be omitted.

Comments from Dr. Richard Smith

1. Were the charge questions adequately addressed?

Yes, all eight draft questions were dealt with in detail and I do not find any omissions. The level of technical detail is impressive.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report.

No "errors" as such, but there is one point where I would have appreciated more detail about what the review panel had in mind.

P. 11, lines 1-5: It was reasonable that the review panel should have asked the question (and provided subsequent data) about the percentages of facilities screened out by past Tier 1 procedures. However, the percentages themselves do not provide adequate information about the effectiveness of the procedures – there needs to be some consideration also of whether facilities are being misclassified. This is connected to the next point.

p. 12 (specifically, line 9, but there are further comments on this point throughout the review, e.g. p. 17, lines 1-2 and 24, lines 40-41).

The review recommends “probabilistic analysis” but does not go into details about what they mean by this. I briefly reviewed this section of the full report and I agree with the criticism – EPA proposes an algorithm for calculating an exposure and comparing it with a predefined threshold, but does not give any consideration to the statistical error in such a procedure. I presume “probabilistic analysis” is intended to imply that EPA should include some calculation of the statistical error. I agree with this recommendation.

In fact, I feel the review panel should go further. It seems to me that, generally, there is a need for more rigorous statistical methodology in the proposed procedures. Traditionally, this would be framed in terms of having a null hypothesis and an alternative hypothesis and calculating the rates of Type I and Type II errors. It is not entirely clear how this would translate to the present context, e.g. how exactly the null and alternative hypotheses would be defined. Alternatively, one might evaluate the proposed procedures more directly in terms of probabilities of false positives and probabilities of false negatives. Possibly this is what the review panel had in mind. However it is framed, I would urge more discussion of this issue.

3. Is the draft report clear and logical?

Yes, the report is well written and logical.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes.

Minor typographical issues:

p. 11, line 28: parenthesis is opened but not closed. The meaning of the resulting sentence could change depending on exact where the closing parenthesis is inserted.

p. 27, line 38: rationale

Comments from Dr. Jeanne VanBriesen

1. Were the charge questions adequately addressed?

Yes

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

No.

3. Is the draft report clear and logical?

Yes. The report is very clear and logical. It is very well written.

There are a few places where word choice should be reviewed to ensure it represents the intent.

p.4 line 33. “EPA should . . . and could . . .” and p.4 Line 35 “should be evaluated” and p.4. Line 36 “SAB suggests EPA evaluation” Are these recommendations or suggestions?

p. 11, line 40 It is not clear what “obviously low-risk sites” means in this context.

p. 12, lines 31-32 It is not clear how the possibility of errors and their policy implications would be considered. Can the committee provide further information

p. 13 lines 7-9. Is the intent to advise EPA to compare the estimates? Is this a suggestions or a

recommendation.

p. 22, line 37 “may offer too much health protection” I think the authors may mean “may be overly conservative”

p. 25. Footnote. Why isn't this a reference like others? Why a footnote?

p. 11, line 30 missing closed parentheses

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes. The report provides excellent and clear recommendations supported by the body of the report.

Comments from Dr. Donald vanderVaart

I have reviewed the draft report by the SAB of an EPA draft screening tool for use in RTRs. I have not reviewed the EPA report itself, but rather the draft review of that report done by the SAB. To help me understand the topic, I also reviewed the EPA's multi-HEM3 and RTR modeling guide.

Much in the SAB report speaks to the reasonableness and accuracy of the approach. The EPA's approach includes a 3 tier approach to evaluating sources for their impact on surrounding residents for possible additional emission requirements under section 112(f).

To understand the accuracy needs of this exercise, it is important to understand how it will be used. So my first question is whether how it will be used is clear to everyone.

Question 1: Sources to be evaluated by this technique have already been required to install technology standards under section 112(d). These standards apply to all sources within the source category. For example, for the source category of “aluminum widgets” there may be 30 facilities nationwide. Each of these facilities has installed the 112(d) technology and comply with the 112(d) emission standard. Congress directs EPA to determine whether a more stringent standard is necessary to provide an adequate margin of safety, as specified in Section 112 as it existed prior to the Clean Air Act Amendments of 1990. Section 112(f)(2)(b) references to the Benzene NESHAP (54 FR 38044) as the basis for determining an ample margin of safety. That notice requires cost-benefit and other analyses in determining the availability of additional standards for any risk greater than 10^{-6} . Section 112(f) provides that if any facility in the category represents a greater than 1 in a million (10^{-6}) additional risk of cancer, the Administrator is to set an additional standard consistent with the methods used in the Benzene NESHAP. The Benzene NESHAP looks at costs, feasibility, and other factors when evaluating possible strategies for lowering risk to below 1 in 10^{-6} . The screening tool is meant to provide EPA a means of evaluating risks from each and every post-112(d) controlled facility within each source category. Two scenarios are possible after implementation of 112(d) technology standards.

1 – All facilities within the source category represent a less than 10^{-6} risk. No additional regulation is needed.

2 – While some facilities represent a less than 10^{-6} risk, some represent a greater than 10^{-6} risk.

The higher risk facilities would require evaluation to determine whether cost-effective regulation is available to lower the risk. What is cost-effective for those facilities may not be cost effective

for the lower risk facilities due to the lower benefit any additional controls would bring. The consensus appears to be that, at least Tier 1 of, the screening tool is conservative. This is reasonable. If all 30 aluminum widget makers screen below a 10^{-6} risk, the EPA's job is done. In the second case some additional regulatory requirements are indicated.

Question 2 – If, even after Tier 3 is used, there are one or more facilities with a risk greater than 10^{-6} , are facilities or trade associations provided an opportunity to present their own risk analysis for consideration for the facilities still predicted to exceed the 10^{-6} risk?

This would provide a back-stop for the process as a whole since only the remaining facilities would need to be scrutinized at a level of detail greater than Tier 3. Knowing that this analysis will be done also provides some relief in spending too many resources on developing an absolutely perfectly accurate Tier 3 analysis.

Question 3 – If some facilities represent a higher risk than 10^{-6} risk, will all of the facilities be subject to the new requirement, or only those with risk greater than 10^{-6} ?

If, say, 24 of the facilities screen out under Tier 1 as representing less than a 10^{-6} risk, and if only 24 facilities existed in the source category, then no additional regulation would be required. In our example there are 30 facilities in the category so does the answer change for those 24 low-risk facilities? Since the statutory threshold is 10^{-6} and the Benzene NESHAP test is to provide risk levels of less than 10^{-6} to as many as possible, the 24 facilities that already provide that level of protection would not need be further addressed.

Generally, there are indications that emissions are being overestimated. In the Multi-HEM3 modeling guidance it is recommended that a rate many times the annual emission rate should be used for short term emission rates when evaluating short term impacts. Are actual emission rates being used to evaluate facilities or are potential emissions being used? There are reports that TRI emissions are being used at times which are notorious for over-representing facility emissions. In other cases, emission inventories do not distinguish between HAP compounds from MACT sources and those coming from other sources. This is essentially a manifestation of the different emission inventory requirements from state to state. How are these cases being handled?

Again, over-estimation of HAP emissions are certainly understandable, but at higher levels of scrutiny, what assumptions have been made are important to inform how emission inventories may be refined.

Comments from Dr. Kimberly White

1) Were the charge questions to the committee adequately addressed?

All eight charge questions appear to be adequately addressed as detailed on pages 10-29 of the draft report.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

There does not appear to be any technical errors or omissions or issues that are not adequately

dealt with in the draft report. The SAB panel specifically noted in their report when there were omissions that limited their review (e.g. insufficient census block receptor check tool information, information on overall effectiveness of the screening methods).

3) Is the draft report clear and logical?

The draft report is clearly written and logically organized.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Overall, the recommendations and conclusions provided by the SAB panel are supported, and references or specific examples provided where applicable, in the body of the report.

One suggestion is provided here where the SAB panel could provide some additional elaboration on a recommendation noted in the draft report. On page 5, lines 16-17 and page 24, lines 3-4 the SAB panel notes that selenium is not included as a chemical to screen and recommends that it be considered for inclusion. However, the SAB panel provides limited information regarding the “potentially important role in ecological impacts” that would support including selenium. It is recommended that the SAB panel add this information to the draft report.

Minor editorial comments:

- Cover letter, page 2, line 3. Strikethrough text as follows: “.....RTR document and and the effort...”
- Cover letter, page 2, line 8. Insert underlined text as follows: “Insufficient detail was provided in the Agency’s...”
- Draft report, page 8, line 21-22. The following sentence seems unclear and should be reworded. “For example, the 1996 assessment did have census block-level resolution, but rather was performed at the census tract level.”

Comments from Dr. S. Stanley Young

1. Were the charge questions adequately addressed?

With any question there are presumed true background facts. For example, to control an air component, one presumes that the component at current levels has adverse effects. Large, recent studies call causality into question. SAB should consider a reappraisal of presumed true facts.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

Several items seem either too small to consider or should be delegated to the states as conditions vary over the US.

3. Is the draft report clear and logical?

Some things sound fine but seem to be hair-splitting relative to the imprecision of the available data.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

I think some of the “known facts” need to be reevaluated considering recent literature. See references Greven, Milojevic, Young, for example.

The written comments do not need to repeat the original charge questions or summarize the report; it is most helpful if they simply directly address the four quality review questions.

Specific comments:

Letter. Page 1. Line 17

“EPA’s methods for conducting initial risk screening analyses in the Clean Air Act mandated assessment of “residual risk”, i.e., **the risks remaining** after application of maximum achievable control technology pursuant to the National Emission Standards for Hazardous Air Pollutants under Title I of the Clean Air Act.”

There are recent studies that find no effect of current air quality on mortality and heart attacks. These studies call into question current air quality as causal of mortality health effects. There may be no residual risk remaining. See Greven et al. (2011), Milojevic et al. (2014), and Young et al. (2017).

Letter. Page 2. Line 10.

“...EPA explore a transition for its screening methodology...”

Some estimates of the fraction of sites are given, e.g. Tier 1 screens out 30% of sites. I agree that it would be useful to compile previous data to get better estimates and determine the factors related to passing or not screens. It might be useful to run a pilot study using different screening criteria in different regions to see what factors might affect health outcomes. See Chay et al. (2003) and Obenchain and Young (2017).

Letter. Page 2. Line 27.

“... lifetime average daily dose...”

The appears to assume cumulative toxicity. Is there any bases for this assumption? Does the basis change, depending on the agent?

Letter. Page 2. Line 27.

“...inclusion of the gardener scenario..”

I support the misgivings of the SAB. Just how many of the US 330m people are gardeners? Gardeners seems more the business of the states.

Letter. Page 2. Footnote.

“... reference substance(s) within the group...”

Clustering compounds is a complex area of research with publications coming from the drug industry. See Rusinko et al. (1999), Young et al. (2001), and Feng et al. (2003). Compounds with known outcomes can be put through a data mining methodology, Recursive Partitioning, to model the outcome and the model be used to cluster compounds and predict compounds with unknown outcome.

Draft. Page 3. Line 9.

“...the SAB could not assess the overall operational effectiveness of the screening methods..”

The analysis of existing screening data seems in order, followed by a pilot study to see what factors affect screening outcomes. Also, heterogeneity of health effects of air quality should be examined in detail to help determine what factors might relate to health effects. See Smith et al. (2009), and Obenchain and Young (2017).

Draft. Page 3. Line 25.

“..starting with health protective parameters..”

New studies on air quality and health effects do not agree with older studies. The EPA should evaluate recent papers on PM2.5 and ozone. See Greven et al. (2011), Milojevic et al. (2014), and Young et al. (2017).

Draft. Page 3. Line 36.

“...EPA’s past efforts to ensure RTR input data accuracy...”

EPA should follow the Data Quality Act, which includes making data available. Given the realization that many science claims fail to replicate, independent replication of randomly selected studies appears to make sense.

Draft. Page 4. Lines 3 and 21.

“... statistical analysis...”

Any such effort should have sound statistical input from a professional statistician. How many statisticians does the EPA employ? The FDA has many. Hundreds?

Draft. Page 4. Line 26ff.

The characteristics of sport fishing seem rather local to me and might better be judged by states rather than feds.

Draft. Page 5. Line 1ff.

“The SAB agrees that the proposed gardener scenario is an appropriate addition to both Tier 1, 2 and Tier 3 screening evaluation.”

How many of 330M citizens garden? Are any of them killed? What is the value of a statistical life saved here? My experience is that companies provide instructions for use of their products. Trial lawyers are on the job. Is it cost effective to do more?

Draft. Page 5. Line 16. Selenium

Selenium is a trace mineral essential to good health. The major dietary source of selenium is plant foods. What is the evidence for selenium overdose? Would adding selenium be cost effect relative to value of statistical life?

Draft. Page 5. Line 27.

“...the number and placement of new receptors.”

More information is needed to comment on this.

Draft. Page 6. Line 36.

HAP - Hazardous Air Pollutant

Hazzard depends on the toxicity of the chemical and the level of exposure. The word "Pollutant" seems redundant and even inflammatory. I would replace pollutant with component everywhere. Words matter.

Draft. Page 8. Line 42.

Administrator Johnson. ?Correct person?

Draft. Page 9. Line 19.

It is difficult to believe that homegrown fruits and vegetables are a national problem. EPA should consider moving this work to the states.

Draft. Page 10. Line 38.

Rules should be clear. As noted above, it makes sense to pilot different rules at different locations (an experiment) and note if which rules have beneficial effect.

Draft. Page 11. Line 34ff. Page 12. Line 17

Safety factor can combine with safety factor until the combined effect is very far from reasonable. In parallel to giving safety factors, the median risk at each stage should be determined and given.

The EPA should commit to requiring the EPA to follow the Data Quality Act, which includes making analysis data public.

Draft. Page 12. Line 41.

Normally the FDA deals with food. Are the EPA and FDA coordinating?

Draft. Page 13. Line 3.

CDC (NHANES) monitors ~250 chemicals in urine. Is EPA coordinating with CDC? Is there any association of these chemicals with health outcomes? Until there is, regulation should be minimal. See Young and Yu (2009). There is a serious statistical problem with examination of monitoring data. There are typically multiple health effects and multiple exposures, so the number of statistical comparisons can be very large. The statistical analysis should take multiple testing into account.

Draft. Page 13. Line 17.

Sport fishing seems a minor component of US food. Are any lives lost? What is the value of a statistical life for this situation? Move that function to states.

Draft. Page 13. Line 28.

Dioxin is a class, not a chemical. There are 135 possible isomers depending on the number and placement of the chlorine atoms. The "dioxin" that worries people is 2,3,7,8-Tetrachlorodibenzo-p-dioxin aka TCDD. TCDD is set up perfectly to fit into DNA grooves, which is the reason for its carcinogenicity/mutagenicity (barely). But TCDD is no longer being produced. It was an impurity in the synthesis of 2,4,5-T, one of the two herbicides used in Vietnam (the other was 2,4-D, which you can buy in any Home Depot. (The two together were called Agent Orange). It is chemically impossible to form TCDD from 2,4-D now that 2,4,5-T is banned, so the problem is essentially gone.

Viktor Andriyovych Yushchenko born February 23, 1954) is a Ukrainian politician who was the third President of Ukraine from January 23, 2005 to February 25, 2010.

As an informal leader of the Ukrainian opposition coalition, he was one of the two main candidates in the 2004 Ukrainian presidential election. Yushchenko won the presidency through a repeat runoff election between him and Prime Minister Viktor Yanukovich. The Ukrainian Supreme Court called for the runoff election to be repeated because of widespread electoral fraud in favor of Viktor Yanukovich in the original vote. Yushchenko won in the revote (52% to

44%). Public protests prompted by the electoral fraud played a major role in that presidential election and led to Ukraine's Orange Revolution.

Following an assassination attempt in late 2004 during his election campaign, Yushchenko was confirmed to have ingested hazardous amounts of TCDD, the most potent dioxin and a contaminant in Agent Orange. He suffered disfigurement as a result of the poisoning, but has since made a full physical recovery.

It appears that dioxin is much more toxic in rodents than man.

Draft. Page 13. Line 35.

Epidemiology claims most often fail to replicate. Until an epidemiology claim is independently replicated it should not be used for regulatory decisions. Any Epi study should follow the Data Quality Act, which includes public access to the analysis data set used in the study.

Young SS, Karr A. Deming, data and observational studies: a process out of control and needing fixing. *Significance* 2011; 8: 122-126.

Draft. Page 17. Line 10. Fishing, lake and pond assumptions.

I find this whole scenario problematic as a national question. These problems would best be left to the states.

Subsistence/fishing seems more likely to be a state specific problem and best left to the states.

Draft. Page 18. Line 26.

“...This process may become more transparent if the data are presented with information about how studies were included or excluded...”

The literature is vast and there are often papers on both sides of a question. By selective citation, either side of a question can be made to look reasonable.

Draft. Page 19. Line 34.

“A guiding principle should be “documented and reproducible” such that independent experts can understand the data and methods applied by EPA analysts and can reproduce the results.”

Agree. That should hold for environmental epidemiology research funded by EPA.

Draft. Page 21. Line 17.

I find this gardener scenario problematic primarily because it would be such a small fraction of the US population. If it is reasonable at all, it would seem to be state specific.

Draft. Page 23. Line 3.

“...ecological assessment endpoints..”

What are the specific endpoints? Chemical levels? Adverse effects on biological organisms?

Ecological benchmarks are likely very locally specific, better determined by the states. For example, PM2.5 composition varies with time and place.

Items should have some sort of tolerance for chance variations. As the number of elements is increased these tolerances should be increased. As more items are examined, chance can lead to some item being outside tolerance bounds.

Draft. Page 24. Line 12. BaP is what?

Draft Page 24. Line 24ff. Line 31.

This all sounds reasonable, but it is very open-ended. There should be a limited number of "trip-wire" items.

I find "The Klimisch evaluation criteria can split opinions and prompt fierce debate. Used to assess the reliability of toxicological studies, they help guide risk ... a high probability that different assessors would assign different scores to the same study."

I will add that toxicology studies most often do not consider the number of endpoints so there are likely many false associations. Many years ago, I counted out the number of endpoints in several long-term rodent studies. As I remember, there were hundreds of tests for this or that tumor, males, females, rats, mice were all tested separately. False positives are inevitable. The reliability of toxicology studies is in question.

Draft. Page 27 Census block receptor check tool

All this sounds reasonable, but it assumes a level of precision both for air component level and health effect that is not realistic.

Draft. Page 30. References.

It would help to have key primary references identified.

References

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