Preliminary Panelist Responses to Charge Questions
Compiled for
SAB Risk and Technology Review (RTR) Method Review Panel

Comments Received as of June 28, 2017

Contents

David A. Eastmond, ... 2
Dale Hattis 5
Gary Ginsberg 14
Slawo Lomnicki 18
Veronica Vieira 20
Charles T. Driscoll 22

David A. Eastmond,

University of California, Riverside

June 24, 2017

Charge Question 1: Does the SAB find that the three-tiered multipathway risk screening approach appropriately eliminates from further consideration those facilities unlikely to emit PB-HAP in concentrations resulting in appreciable multipathway risk and identifies those facilities where additional multipathway analysis may be warranted? Does the SAB have specific suggestions for improvement of the risk screening methodology?

The use of the 3-tier multi-pathway risk screening approach developed by the EPA seems to be reasonable and logical. It has the potential to focus agency time and resources on sites of most concern from a public health point of view. However, I am not able to determine at this time whether it will be effective in screening out low-risk facilities and focusing attention on high-risk facilities. From my perspective, the best and maybe only way to really know if the 3-tiered approach will work as desired is for the Agency to identify the screening goals that the Agency would like to achieve, and then apply the 3-tiered approach on actual sites, either new ones or ones that have previously been evaluated, and determine how well the approach achieves its goals.

The Tier 1 approach contains a considerable number of health-protective assumptions or parameters so that the potential risk for a large number of individual facilities is likely to be overestimated, and substantially overestimated because multiple health-protective parameters are being used. If, even with this over-estimation, the agency is able to screen out the majority of low-risk facilities, then I would consider it to be successful. It is likely that the approach will need additional modification and calibration to achieve the Agency goals. This will need to be done during the roll-out of the method, and the Agency should be given the flexibility to adjust its methods as needed to achieve its screening goals.

While it is desirable to be able to screen out sites with the lowest risk, for those deemed to have intermediate and high risks, it might be more useful to use this approach to prioritize sites for further study. Screening out implies that it is no longer of concern. In some cases, it may be advisable to keep a site on the list but assign it a low priority for further investigation.

<u>Other considerations</u>

On page 16 lines 6-8, the report indicates that “dermal absorption of originally airborne chemicals similarly has been shown to be a relatively minor exposure pathway compared

with other pathways" and cites one report from 2000 and another from 2006 to support the statement. I suggest that the Agency investigate if the evidence still supports that conclusion and applies to all classes of chemicals. More recently, there have been several studies from well-regarded scientists (Weschler and Nazaroff, 2012, 2014; Morrison et al., 2016) that have suggested that dermal absorption of certain classes of chemical can contribute significantly to a person's overall dose.

While it may be outside the scope of this review, I do wonder what types of action the Agency would plan to take when a source contributes a small but significant fraction (e.g. 10-20%) to the overall dietary burden of a common environmental pollutant such as methylmercury which is clearly associated with adverse health effects.

If it has not yet been done, I recommend that the accuracy of the calculations generated by the various software packages being used for the screening assessment be thoroughly checked before its widespread usage for this project.

Charge Question 3: Does the SAB find that the assumptions for human fishing behavior used in the refined fisher scenario, the assumptions about PB-HAP deposition to lakes, and the assumptions on the ability of ponds and lakes to sustain populations of fish are appropriate?

Most of the assumptions/parameters seem very health protective but not unreasonable given the objectives of the screen. However, since the overall scenario is indicated by the EPA as being highly unlikely, I wonder if a more realistic ingestion rates and parameters should be employed. I am unable to advise on specific values as it is outside of my expertise. As indicated above, the use of multiple health-protective assumptions/parameters is likely to overestimate the actual risks, probably by a substantial margin.

Subsistence fisher should be defined and the amounts of fish that s/he are estimated to eat should be presented. On page 42, refined and unrefined fisher should be defined in a footnote.

To me, it seems unlikely that a subsistence fisherman would travel long distances to fish as s/he is probably doing the fishing to save money and traveling 30-50 km would increase costs.

Other comments
The definition of $RefMix_{T2}$ should be added to Equation 6 on page 35.

Charge Question 5: Does the SAB find the assumptions and approaches laid out for

application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

Again, the assumptions/parameters seem quite health protective but not unreasonable given the objectives of the screen. Again, it would be useful to know how often the model scenario would be likely to be seen. The distinction between a rural and urban gardener seems like a valuable addition and would improve the characterization of risks for rural and urban residents.

Other

Exposed vs. protected fruits and vegetables should be defined.

For clarity and for the benefit of the reader, I would recommend that the soil ingestion rates be presented as mg/kg-day rather than mg/day.

The reference in footnote b of Table 3-18 seems to be incorrect as Table 4-23 in the Exposure Factors Handbook describes mouthing duration.

References

Weschler CJ, Nazaroff WW. SVOC exposure indoors: fresh look at dermal pathways. Indoor Air. 2012 Oct;22(5):356-77.

Weschler CJ, Nazaroff WW. Dermal uptake of organic vapors commonly found in indoor air. Environ Sci Technol. 2014 Jan 21;48(2):1230-7.

Morrison GC, Weschler CJ, Bekö G, Koch HM, Salthammer T, Schripp T, Toftum J, Clausen G. Role of clothing in both accelerating and impeding dermal absorption of airborne SVOCs. J Expo Sci Environ Epidemiol. 2016 Jan-Feb;26(1):113-8.

Dale Hattis

Draft 6/16/17

Screening methodology review notes and comments for Charge Question 2

Charge Question 2: Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

Summary response:

The analysis provided in Section 3 of the document is completely inadequate to evaluate the question of whether the many choices made in crafting the risk equivalence factor methodology together "appropriately" account "for differences in the environmental fate and transport among polycyclic organic matter and dioxin congeners." Even a purely technical evaluation of the system is impossible without complete documentation of the many parameter values chosen as essential components of the methodology, and the underlying uncertainty distributions from which the single-point values were selected. A meaningful analysis of the effects of the choices in the different screening tiers requires a full probabilistic analysis of the combined effects of the multiple parameter choices in the context of the underlying probability distributions for all the uncertain parameters. Taking the further step of assessing whether the combination of these choices of parameter values "appropriately" represents the fate and transport of the individual congeners involves a risk management judgment that is beyond the scope of a technical review committee.

More detailed notes and comments directed to specific places in the document relevant to charge question 2:

EPA uses these screens to quickly identify those facilities in particular stationary source categories that have little potential for human health or environmental risk,
while also identifying those facilities where a refined risk assessment might be needed

p. 15
We parameterized the physical/chemical environment represented in the screening scenario by using health-protective values for certain parameters to which chemical exposures are especially sensitive.8 This approach tends to overestimate concentrations in the media that drive ingestion exposures for humans. Some of the more health-protective assumptions in the Tier 1 screening scenario include:

Low wind speeds (more chemical deposition to the nearby lake and farm relative to higher wind speeds).

Low mixing heights (higher chemical concentrations in the mixed layer of air next to the ground relative to higher mixing heights).

High precipitation rates (higher chemical deposition relative to lower precipitation rates).

Winds frequently blowing chemical emissions toward the lake and farm, and, as previously mentioned,

watershed characteristics that enhance chemical loading to the lake and farm via erosion and runoff.

This basic methodology—multiplying supposedly "conservative" values of several uncertain factors—is profoundly deficient. EPA has used this in the past many times, but it is high time EPA should routinely do probabilistic analyses combining the effects of distributions of multiple uncertain factors into a coherent analysis from which arithmetic means and specific "conservative" fractiles could be derived. Anything less is simply not sustainable as a modern analysis.

Moreover, The document in its present form does not even appear to provide reviewers or the public with the actual single-point allegedly conservative values chosen for these parameters in the sceening analyses. Without these values and the distributions they come from, no evaluation of whether the set of values "adequately accounts" for differences in environmental fate and transport among the different chemicals is possible.

Testing this methodology could involve a series of comparisons of the screening predictions with later results of full analyses.

The conclusion reached by the authors is, "the probability of such risk-maximizing environmental conditions prevailing across multiple meteorological parameters over the course of the entire year is very low."

This does seem likely, but no quantitative evaluation of it is possible without at least a rudimentary probabilistic analysis where the individual factors are characterized as uncertainty distributions and the product of all the factors is evaluated via simulations of multiple iterations in Excel or other common quantitative modeling tools.

p. 18

The multipathway screen the SAB previously reviewed did not account for differences in environmental fate and transport among POM or dioxin congeners (i.e., all POM

congeners were assumed to move, partition, and degrade in the environment as BaP does, and all dioxins were assumed to exhibit the same fate and transport as 2,3,7,8-TCDD). The new REF approach includes an exposure-equivalency factor (EEF) that reflects an individual chemical's fate and transport relative to the index chemical for each group (BaP for POM and 2,3,7,8-TCDD for
dioxin). The REF equals the product of the chemical-specific EEF and the chemical-specific toxic equivalency factor (TEF), the ratio of the congener's oral toxicity to that of the index chemical, as shown in Equation 1 below

[equation missing]

toxic equivalency factor just multiplied by an index of exposure

EEFs represent the ratio of the exposure to a particular congener to the exposure to the index chemical at equivalent emission rates. EEF varies across chemicals, depending on the values for various properties that influence environmental fate and transport (e.g., Kow [octanol-water partition coefficient], intermedia partition coefficients, molecular weight, half-life, potential for biodegradation). EEFs for a given congener change as environmental conditions change and vary with distance from the source. That means EEFs in the multipathway screens differ across the tiers because they depend on lake location, farm location, and meteorological conditions used.

Exposure where? To what receptor? Located where relative to the emission?

Linear with kow?
Intermedia partition?
Molecular weight
Half life
Environmental conditions???
Distance from source

p. 19

For most of these congeners, we used Kow-based regression estimates to develop EEFs (refer to Figure 3-2, which illustrates a strong and direct correlation between Kow and exposure).

We evaluated the relationships between chemical-specific properties (e.g., Kow, Henry's Law Constant) and intermediate modeled values (e.g., deposition rate, soil concentration) and exposure. The correlation between Kow and exposure is stronger than for any other chemical-specific property. For POM congeners not characterized in TRIM.FaTE and MIRC, we interpolated age-adjusted LADDs—an estimate of exposure—using the chemical's Kow value in a power regression based on the modeled POMs

pp 19-20

For unspecified POM compounds (i.e., reported as "PAH, total", "polycyclic organic matter", and "benz[a]anthracene/chrysene"), we assumed Kow values near the upper end of the range across all congeners (a health-protective assumption). In addition, due to lack of information on the Kow for benzo[b+k]fluoranthene, we made a health-protective assumption that
the Kow equaled that of benzo[k]fluoranthene, which has the larger 1 Kow value of the two. Like the EEFs derived from modeling, these regression-derived EEFs also differ across the screening tiers. All dioxin congeners are fully characterized and modeled in TRIM.FaTE.

figure 3-2—really big scatter on a log log graph. Does the resulting central regression relationship represent best estimates in terms of arithmetic mean values over the relevant uncertainties? Use of LADD (or, effectively Log(LADD) as the regression dependent variable risks considerable confusion and misestimation of the desired health-risk-predictive parameter for modeling.

Do the derived relationships with emissions make sense in terms of mass balance—power of about 1 may mean that it does—double check and also quantify uncertainties

Preliminary estimation of scatter from figure 3-2 is done in an excel spreadsheet

General critiques:

> **The goal is set in terms of individual risk to a hypothetical receptor, rather than the aggregate population risk. The latter, instead could be derived from the general "intake fraction" ideas. The individual risk metric in my view focuses exclusively on the equity issues (is there an unfair imposition of risk on individuals at the most at-risk locations, but ignores the population aggregate risk that should also be a focus of environmental health protection.**
>
> **The methodology is, as has often been done in the past by EPA, a combination of multiple single-point factors rather than a full probabilistic analysis. From the analysis provided it is impossible to tell how "conservative" or not the ultimate projections are. Thus it is impossible to say whether the screening system is well calibrated to represent any specific risk management objective for the screening system.**

p. 30:

Based on unit emissions of 1 g/day and taking into account: (1) wind speed, mixing height, and precipitation rate values shown in Table 3-8; (2) lake- and farm-distance values shown in Table 3-9; and (3) spatial layouts shown in Figure 3-1 and Figure 3-4, we conducted a large set of TRIM.FaTE and MIRC modeling runs. These runs systematically varied each parameter so that all possible combinations were evaluated. The result of this analysis was a matrix of screening level risk estimates based on each unique combination of PB-HAP and values for wind speed, mixing height, precipitation rate, and distance from the facility to a lake or farm.

Why were the results of these analyses not presented to the SAB for systematic evaluation and analysis?

p. 32:

For mixing height, the screening threshold emission rates and REFs are derived using a mixing height value of 226 m (i.e., the Tier 1 mixing height).16 Moreover, as in the Tier 1 screen, the Tier 2 screening threshold emission rate is defined as the emission rate necessary to reach a 1-in-one million excess lifetime cancer risk or an HQ of 1 for a given PB-HAP. Also similar to the Tier 1 screen, the REFs in the Tier 2 screen reflect an individual POM or dioxin chemical's fate, transport, and toxicity relative to the index chemical for each group (BaP for POM and 2,3,7,8-TCDD for dioxin; see Section 3.1.2). We finally note that the Tier 2 screen assesses potential risk from fish ingestion separately from farm-food and soil ingestion, and therefore, there is one library of screening threshold emission rates for fish ingestion and a separate library for farm-food and soil ingestion.

So finally we get information on one of the single-point "conservative" values chosen for the analysis, but no explanation of why this particular value was selected from the universe of possible values, and what percentile it represents for either a local or national distribution.

Because of the more direct and predictable effects of mixing 1 heights on concentrations of chemical in the air and environmental media and (2) the wide range of median mixing heights across the 823 meteorological stations (i.e., less than 200 m to more than 2,000 m, we used the matrix of risk estimates just described above to further quantify the relationship between mixing height and risk. We found that mixing heights share an exponential relationship with the screening-level risk estimates described above. That is, decreases in mixing height lead to exponential increases in risk.

This relationship should be spelled out in algebra.

These exponential relationships are specific to each combination of PB-HAP, distance from facility to lake or farm, wind speed, and precipitation amount. Therefore, for each of these combinations, we used their corresponding screening-level risk estimates to derive a power-curve regression equation that relates changes in mixing height (i.e., the four values used in the modeling) to changes in risk. From this curve, we then were able to derive a matrix of power-curve regression coefficients based on each combination of values.

What was this matrix of results?

These power-curve regression coefficients ultimately are used to adjust the ratio between a facility's actual emissions and a Tier 2 screening threshold emission rate (i.e., the Tier 2 SV) to reflect the effects on risk of the actual mixing height near a facility more accurately.

The annual median mixing height value for the facility's matching meteorological station then is used with the mixing height regression coefficients from the Tier 2 library to develop a site-specific refinement factor incorporated into the calculation of the facility's Tier 2 SV, as discussed later in this section. This mixing height refinement factor is calculated as

Why is it the median that is used, or a simulation of mean and percentile values for the equation derived from the distribution of the uncertain components of Equation 4.

p. 36-8

Early in the process of compiling the Tier 2 lake database, we encountered the question: "What size water body qualifies as a 'lake' for the purposes of this assessment?" The Tier 2 screen must focus on lakes large enough to support relatively intensive fishing pressure to be compatible with the high-end fish ingestion rates assumed for the exposure scenario (i.e., 373 grams/day).

Well, we now have a revelation of another of the single-point factors—fish ingestion rate at 373 grams/day.

373/453.6 = 0.82 pounds per day

To estimate the relationship between high human fish-consumption rates, harvest rates, and lake area, we made eight key assumptions, listed below. Appendix A provides

information and citations to peer-reviewed literature supporting these assumptions. 1. Very small ponds/lakes (e.g., <1 acre) might not support more than three trophic levels, given the size constraints on total lake productivity (e.g., algal and invertebrate productivity) (Brönmark and Weisner 1996).

2. In larger lakes, piscivorous fish (i.e., WCC TL4 and BC TL3.5) might comprise approximately 20–22 percent of the total fish biomass (Appendix A, Sections A.1.3 and A.5.3).

3. Productivity in most lakes of small to moderate size depends substantially on the benthos, with benthic invertebrates consuming detritus. We expect more biomass in the BC than in the WCC compartment. Assuming 21 percent of the standing biomass of fish is piscivorous, BC fish might account for 17.5 percent of the total standing fish biomass, and WCC fish might account for 3.5 percent of the total fish biomass (see Appendix A, Sections A.1.3 and A.5.3). The remaining approximately 80 percent would include "pan" fish (e.g., sunfish, perch), minnows, and young-of-the-year of piscivorous fish. This set 1 of assumptions represents a "point estimate" of fish biomass in different compartments.

4. Humans consume fish from the BC compartment and the WCC compartment with a 50:50 split, reflecting fishing and consumption preferences rather than relative availability of fish in the BC and WCC compartments (which would result in a ratio closer to 80:20 of BC to WCC consumption). Depending on the chemical, bioaccumulation over 4.0 trophic transfers might result in higher concentrations in the WCC fish compartment than bioaccumulation over 3.5
trophic transfers in the BC fish compartment. On the other hand, for chemicals that partition primarily to the sediment compartment, benthic invertebrates might accumulate more chemical, resulting in higher concentrations in the BC fish compartment than in the WCC compartment. Because we could not predict, a priori, which fish compartment—WCC or BC—would have higher chemical concentrations for any of the chemicals, we assumed the 50:50 split in fish harvested from the WCC and BC compartments. 5. The total fish standing biomass is assumed 40 g wet weight/m2, which might represent relatively high productivity for natural ponds and lakes across much of the United States. Leidy and Jenkins (1977) found the mean total fish biomass of 61 reservoirs to be 41.3 g[fish ww]/m2 (± 30.4 g/m2), with median 30.9 g[fish ww]/m2. We assume that reservoirs tend to be larger and shallower than natural lakes and therefore might have higher primary production than natural lakes. Additional data on total fish biomass measured in several lakes that suggest lower productivities in general are provided in Appendix A, Section A.5.

Overestimates of lake productivity would bias results to be more health protective, because more fish could be harvested from the more contaminated lakes closer to a facility.

6. We assume that the minimum viable population (MVP) size for a single fish species is at least 50 adult fish for a local population to survive over the short term (e.g., more than a decade) (Shaffer 1981, 1987; Appendix A, Section A.3.3). Interbreeding populations of 500 breeding adults (with 50:50 male:female) or more should be sustainable without signs of inbreeding depression. Actual MVP for a population genome depends on many

factors and varies substantially across different species and landscapes. To model MVP for a given species and location, one should specify the timeframe of concern (e.g., 50 years, 100 years) and a target probability of local extirpation (e.g., less than 5 percent). Population modeling for individual species is beyond the scope of RTR screens; we therefore 1 use the estimate of at least 50 breeding individuals to maintain a fish species in a lake (Appendix A, Section A.3.3).
4 7. Humans can harvest 10 percent of any single fish compartment without threatening the population due to overharvesting. Although sustainable harvest rates vary with species life history characteristics, for top carnivores, data suggest that 10-percent harvest rates should prevent overfishing (see Section A.3.4).

10% over what time period? Surely not every day!

8 8. Only 33 percent of the fish caught for consumption is edible fillet muscle (Ebert et al. 1993). A 0.33-edible fraction is used to estimate total fish biomass that must be harvested for human consumption of fillet only.

Charge Question 5: Does the SAB find the assumptions and approaches laid out for application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

Section 3.4 of the report describes a gardening exposure scenario we are considering adding to the Tier 3 multipathway screen. The gardening exposure scenario could help us to better characterize multipathway risk in some instances, especially in locations where the presence of a subsistence farm is either unlikely (e.g., in urban areas) or difficult to confirm based on the characterization of land use surrounding a facility.

As for question 2, the analysis continues the practice of selecting individual "conservative" point values for input to a risk analysis, rather than performing an appropriate probabilistic analysis representing the variability and uncertainty in the individual numbers selected to represent the urban and rural gardeners' ingestion rates for home grown food, garden soil, etc. There is no way to tell exactly how "conservative" the resulting numbers really are and thus risk managers using the results of these calculations can have no idea how health protective they are being in making risk management choices based on them. A probabilistic analysis would allow assessments of the full range of percentiles of likely exposures, and assessment of arithmetic mean exposures and risks needed for choices based on juxtapositions of costs and benefits of alternative regulatory scenarios.

It is also unsatisfactory that the authors have not discussed the issue of what fraction of food the home gardeners consume from their own plots, vs purchased food. The home gardener will necessarily have produce available from his/her own plots for only a portion of the year. Some home-grown produce can of course be stored for later consumption, but it is hard to imagine that much home grown fresh corn, etc. will be available beyond the fall harvest season. Snow-covered gardens are an unlikely source of much consumption, and there surely must be some time before spring plantings yield much for the table. Some adjustments must be made for this in order for gardener scenarios to be realistic.

Inhalation Risk Assessment Enhancements (Chapter 5):

Urban/Rural Dispersion Selection Tool

In previous chronic inhalation risk assessments, we assumed the land surrounding each facility was rural. Since the most recent SAB review in 2009, we developed an urban/rural enhancement to the chronic inhalation risk assessment that allows us to account for the urban/rural characteristics of the land surrounding each evaluated facility, and therefore, to better characterize the dispersion of pollutants near sources (Section 5.1).

Charge Question 7: Does the SAB find that the Urban/Rural Dispersion Selection Enhancement Tool is an appropriate procedure for identifying facilities to be modeled using the urban option in AERMOD?

The procedure outlined seems to call for a completely dichotomous treatment of land use patterns (and resulting dispersion modeling distinctions) as either urban or rural. Clearly, however, the examples given show that most cases are intermediate—with some facilities having more or less urban land use character. Why would it not be reasonable to treat this distinction as a continuous variable, with some appropriate mixture of what would be modeled for urban vs rural character for the individual facilities being assessed?

Gary Ginsberg,

June 26, 2017
USEPA SAB for RTR Method Review Panel

Charge Question 1: Does the SAB find that the three-tiered multipathway risk screening approach appropriately eliminates from further consideration those facilities unlikely to emit PB-HAP in concentrations resulting in appreciable multipathway risk and identifies those facilities where additional multipathway analysis may be warranted? Does the SAB have specific suggestions for improvement of the risk screening methodology?

It seems quite reasonable to have a multi-tiered risk screening approach that uses very conservative assumptions at the first tier and then increasingly more site-specific and realistic assumptions for subsequent tiers. In such an analytical flow the tendency may be to invoke less health protective assumptions as one endeavors greater realism, but it should also be acknowledged that there may be factors not considered in Tier 1 which could increase risk when making the assessment more realistic. In other words, even though I agree that Tier 1 is highly conservative, it is not necessarily using the most conservative approach in all analytical decisions being made. The most obvious area is with respect to multiple sources in which today or sometime in the future there may be more than one facility in this source category, or in different categories (including even mobile sources) that can substantially contribute to the risk created by the target facility. The multi-tiered draft provided by EPA provides for multiple sources impacting a water body in Tier 2 but not impacting terrestrial (farming) sources. Further, it is excellent that EPA is considering the inclusion of a homegrown produce component in Tiers 2 and 3 as this is one factor not otherwise considered that could be a novel source of substantial exposure if local farms are ruled out (e.g., urban areas).

Across the 3 tiers the risk assessment is focused on individual chemicals rather than cumulative risk except for the summation of chemicals across those which can be grouped within a TEF approach. However, chemicals from different classes may contribute to cancer and similar non-cancer risks but it doesn't appear that this form of cumulative risk has been considered in any of the tiers. For example, this may involve adding the cancer risk for dioxins + POM + arsenic to assess total cancer risk attributable to a particular facility. . While the highly conservative assumptions of Tier 1 may be so health protective to allow cumulative risk to only be a qualitative consideration, this is not obviously the case for Tiers 2 and 3. Thus, cumulative risk should be given consideration for addition to the more refined tiers.

Also, as the screening methodology endeavors for greater site specificity and realism with increasing tier, it should consider whether variability in receptor characteristics that may affect exposure and vulnerability are adequately covered. In Tier 1 the very conservative ingestion rates of locally produced edible products would appear to be

conservative enough to cover any other variance in exposure. For example, ADAFs are used for mutagenic carcinogens (BaP and perhaps the other carcinogenic PAHs?) but is the additional exposure in the first years of life (higher food intake rates per body weight) considered as additional risk factors to go along with cancer risk multipliers? Further, breast milk ingestion under 1 year of age is mentioned for dioxins but the manner in which this pathway is analyzed was not described.

I am not knowledgeable in fisheries resources but its unclear to me that in Tier 2 limiting the fish consumption rate from a local water body due to potential depletion of fish from 1 subsistence fisherman is a plausible limitation. If the waterbody aquatic ecosystem is robust enough to support BC and WCC species I would think that one avid fisherman would not be sufficient to deplete the fish population – however, that is speculation on my part and the document should provide the calculations to show that this would occur. The end result of a number of assumptions and productivity calculations is that no more than 1 gram fish/acre of waterbody can be sustainably removed per day (page 40, lines 7-9). In comparison, the productivity of lakes was 82 kg/hectare/year (N=22 lakes, Randall et al. 2011) which converts to 90 g/acre/day.

It is not clear that Tier 1 would capture an important "PB" chemical, PFOS, as may be released from an industrial source category. Given that the Kow of PFOS is difficult to define, an open question is how would EPA use Trim to model PFOS accumulation in fish, an important exposure pathway for this contaminant. What other chemicals might be problematic in terms of Tier 1, 2 or 3 parameterization and exposure modeling? Is this RTR exercise endeavoring to capture emerging contaminants?

The screening approach does not seem to consider potential future land uses but this concern may be covered by the variety of farming locations modeled in Tier 2 which covers a range of potential sitings relative to the source. Further, incorporation of a home garden should also mitigate this concern, although it is not clear whether this is a Tier 2 or Tier 3 addition. If not until Tier 3, this should be reconsidered.

From the current document I cannot tell how effective Tier 1 is in screening out low concern facilities. It may be that its assumptions are so conservative that very little is screened out. The one example shown for Tier 1 presents emissions that far exceed the SV. Thus, I would suggest that EPA analyze the Tier 1 layer from the perspective of whether it is effective in providing screening and elimination across the various source categories, and if not, then how can it be modified to still be highly health protective but also allow for greater efficiency (e.g., a greater drop out rate).

Charge Question 2: Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

I see the value in the overall concept of REF to efficiently combine exposure and toxicity characteristics into one factor relative to the prototype chemical (BaP or TCDD). However, each read-across extrapolation involves one type of uncertainty or another to try and fill datagaps. We have come to accept the TEF approach for dioxins/furans and PAHs, imperfect as that may be (e.g., based upon comparative potencies in surrogate assays - AhR binding or carcinogenesis on mouse skin). However, the EEF relative exposure approach seems to be less well documented regarding how well it will work in read across fashion. Perhaps it's a matter of incomplete description but it appears that a substantial part of the read across exercise (and totally driving it for data poor chemicals) is the chemical's Kow. While octanol/water is obviously a key predictor of fish, meat and dairy bioaccumulation, it has nothing to do with the "P" part of "PB-HAP" – and that is persistence. It is well known that BaP is not persistent in a wide range of biota and so does not accumulate to the extent predicted by its Kow. This is likely true for other PAHs and perhaps also certain dioxins/furans. How environmental and biological half-life is now considered in calculation of EEF for data rich and data poor chemicals is not described in the documentation but is necessary to an understanding of how this read across works. Figure 3-2 shows a large spread (2 orders of magnitude) in the relationship between Kow and LADD. This variability needs to be explored to further build confidence in and perhaps tweak the EFF approach. A reasonable suggestion is that confidence bounds be estimated for the Fig 3-2 regression slope and consideration given to using an upper bound on LADD rather than the central regression estimate.

The REF approach has not been evaluated for pathways of greatest relevance to early life. If one is using early life ADAFs for carcinogenic PAHs, then should the EEFs also focus on exposure to early life (e.g., partitioning into breast milk or levels found in formula). I would imagine the breast milk pathway would be driven by Kow and biological half-life, with the latter apparently not considered in the REF approach.

Charge Question 5: Does the SAB find the assumptions and approaches laid out for application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

In one place the document states the gardener scenario is being considered for Tiers 2 and 3 but this question is about its use in only Tier 3. Its consideration in both Tiers 2 and 3 would be appropriate since more realistic assessment of land use around a facility may rule out local farm production (e.g., urban, suburban) and so the may terrestrial food ingestion pathway may be local home gardening, which can happen in any land use. The

intake rate assumptions for garden produce for urban and rural gardeners appears reasonable relative to the farm scenario.

One feature that may be reconsidered is the soil ingestion rate for gardeners, which is now considered at 201 mg soil/day. It is appropriate to consider the urban and rural gardener to have high end soil ingestion rates, similar to the farmer. This is because gardening may be considered a high soil contact activity. However, such high soil contact activities can be associated with higher soil ingestion assumptions as exemplified in the outdoor construction worker scenario which the USEPA OSWER supplemental soil guidance (2002) assumes can occur at 330 mg/day. I have also seen risk assessments use 400 mg/d for high soil contact activities. In a warm climate where gardening may occur year round, such high soil ingestion rates may be relevant as the daily average. In colder climates, this may be a seasonal high end value.

June 23, 2017

Slawo Lomnicki

Comments upon the review of the
"Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis"

The presented document emphasizes the changes introduced to the risk assessment protocol as it pertains to the stationary sources of air pollution. The method under the review specifically targets the human endpoints through the ingestion pathway. The previous protocol was based on the one Tier assessment and proved to be too rigorous and did not screen facilities with low health risk. Changes to the risk assessment protocol were introduced and include a multistep screening process to include gradation of the environmental and behavioral parameters assumptions from the more generic (and broadest) to more specific. This creates a 3 Tier process. The panel has been asked to review specific components that are subject of current modifications in the risk assessment protocol, which include risk equivalency factors introduced into the Tier 1 and all screens included in Tier 2 and 3.

Overall the methodology introduced in this revised approach seems to be very reasonable and achieve its goal of gradual screening process of potential human health risk. Introduction of specific human exposure scenarios refines the risks according to the specificity of the location and human activity.

Small refinements, clarification and corrections, however, are advisable to improve the screening process. Below are comments to the assigned charge questions

Charge Question 2: Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

The tier 1 screening process is based on the development of the risk equivalency factors (REF) for different HAPs which encompass their relative toxicity compared to the standard and their environmental fate (meaning partitioning, decay, dissipation and dispersion) after the release. This is a very reasonable approach and reflecting actual state of the HAPs, provided that correct assumption in respect of the fate are in place.

The parameter that defines environmental changes of the HAPs upon release is the EEF (exposure equivalency factor). Unfortunately, very little explanation is provided on how EEFs are developed. It is not clear if they contain such processes as differences in air oxidation, photodegradation, particle partitioning, volatility etc… All these parameters are of critical importance in fate and transport of HAPs. From the discussion in the report it appears that the only discriminator for differentiation of EEF for POMs are the

differences in their Kow (water octanol partitioning). The presented correlation is however weak at places (for example for Kow of ~1E+6 the exposure varies by more than 2 orders of magnitude)

On a separate note

- for Tier 1 screening, different runoff and erosion parameters are set for farm (60%) and lake (100%). There is no explanation provided for such differentiation.
- The ingestion of fish and produce by the humans are set at extremely high rate (100% from local resources). This creates a potential of overestimating the human risk exposure and preventing screening of low risk facilities. Decrease of the ingestion is suggested (maybe 80%)

Charge Question 3: Does the SAB find that the assumptions for human fishing behavior used in the refined fisher scenario, the assumptions about PB-HAP deposition to lakes, and the assumptions on the ability of ponds and lakes to sustain populations of fish are appropriate?

The fishing scenario is in general developed correctly. Some revisions are suggested in respect of the species collected for water column (WCC) or bentic compartment (BC). At present the model assumes 50:50 ratio of fish collected from both compartments. However, as explained in the appendix, benthic fish collection is usually higher compared to WCC species (although preferred) due to the general species abundance. At the same time, majority of POMs and dioxins partition preferentially to the sediments and benthic organism are enriched in pollutants compared to the water column species. Even when considering 1 trophic level difference, this does not account properly to the ingestion exposure.

Charge Question 5: Does the SAB find the assumptions and approaches laid out for application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

Inclusion of a gardener scenario provides an added value to the risk assessment model. Overall the assumptions are correct. One potential refinement can be introduced: the gardener scenario is limited only to the fruits and vegetables, however it is also common that small gardens in urban areas can have a chicken pen and provide eggs to the gardener.

6/28/17 Preliminary Comments for review and deliberations by the RTR Methods Review Panel **Do Not Cite or Quote.** These preliminary comments are draft and a work in progress. They do not reflect consensus advice or recommendations, and have not been reviewed or approved by the chartered SAB and do not represent EPA policy.

Prepared by
Veronica Vieira June 23, 2017

Review of *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (May 2017) with additional reference to *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board: Case Studies –MACT I Petroleum Refining Sources Portland Cement Manufacturing* (June 2009)

Charge Question 2: Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

Response: The risk equivalency factor (REF) is the product of the exposure (EEF) and toxicity equivalency factors (TEF). The EEFs represent the ratio of the exposure to a particular congener to the exposure to the index chemical at equivalent emission rates. However, it is unclear how "exposure" is being calculated. While 22 of the POM congeners are not fully characterized in the TRIM.FaTE model, there are 13 POM and all the dioxin congeners with available data. It is reasonable to expect that the de minimus emission rates can be calculated for two additional congeners to test how well the REF accounts for differences in the fate and transport.

Charge Question 7: Does the SAB find that the Urban/Rural Dispersion Selection Enhancement Tool is an appropriate procedure for identifying facilities to be modeled using the urban option in AERMOD?

Response: The description of the AERMOD Implementation Guidance lacks sufficient detail to understand how classifications are determined with this approach. With the HEM approach, it is possible that a facility would be located on the edge of an urban area so that the closest census block is urban but then the majority of the surrounding area would be rural. A preferable method would be to apply an adjusted land use categorization where the area of water/wetlands (classes 11, 90, 95) is subtracted from the 3-km radius area and then the proportion of urban land use (classes 23 and 24) is calculated.

Charge Question 8: Does the SAB find that the Census Block Receptor Check Tool and associated enhancements are an appropriate method for identifying and adjusting model receptors to ensure the receptors are representative of residential locations?

Response: The highest modeled concentrations are generally within 1km of the facility boundary. Changes to the centroid receptors are made before the model is run, and

presumably saved for all future runs, so that the receptors do not need to be revised again unless changes in the census data indicate a new housing development has been built in the area. With advancements in GIS, it should now be feasible to examine the 1km buffer surrounding all facility boundaries to place receptors that adequately represent the population.
27 June 2017

Response to charge questions and comments for "Review screening methodologies to support risk and technologies reviews: a case study analysis"

Charles T. Driscoll

Department of Civil and Environmental Engineering
Syracuse University
Syracuse NY 13244
ctdrisco@syr.edu

Charge Question 1: Does the SAB find that the three-tiered multipathway risk screening approach appropriately eliminates from further consideration those facilities unlikely to emit PB-HAP in concentrations resulting in appreciable multipathway risk and identifies those facilities where additional multipathway analysis may be warranted? Does the SAB have specific suggestions for improvement of the risk screening methodology?

I endorse the three-tiered multipathway risk screening approach. The approach proposed seems conservative but should efficiently eliminate facilities that emit levels of PB-HAPs that do not pose a threat to significant human and wildlife exposure.

I do have a few suggestions/comments/questions that may be relevant to charge question 1 and other charge questions.

The committee was not asked to comment/review TRIM.FaTE. I am not familiar with this model, but I do have some questions. On the conceptual approach a lake is modeled as the aquatic resource that supplies fish. What is the situation if the region of deposition includes a river/stream/canal or coastal area? Considerable fishing occurs on bodies of water other than lakes. Lakes are not that common outside of the glaciated lands of the U.S.

Based on the limited description in the text, I have concerns that TRIM.FaTE may not do an adequate job simulating the dynamics of mercury. For example, does the model depict the conversion of ionic mercury to methyl mercury? Does the model consider the important role of wetlands and reducing conditions in the production of methylmercury? Does the model consider the important role of forest cover in enhancing deposition of mercury through uptake of atmospheric mercury by foliage and deposition of this mercury as litter? Does it consider the diverse sensitivity of different landscapes (forested, wetland montane) for effects of atmospheric mercury deposition?

If Tier three screening threshold emission rates are exceeded for a facility would there be circumstances where actual site measurements would be made to evaluate if there was risk of elevated exposure of humans or wildlife to one or more contaminants?

How does this assessment account for the effects of non-facility deposition of a contaminant? Several of the HAPs considered undergo long-range transport. A site may be contaminated from regional or global HAP sources or may be highly sensitive, such that the contamination from a facility being examined does not exceed the screening threshold for emission rates, but the increment of contaminant from a facility could contribute to humans or wildlife experiencing un acceptable exposure due to high sensitivity or background deposition.

Along a similar line, I did not see any time scale for the proposed analysis. Several of the HAPs considered either do not degrade or degrade slowly. If a facility operates over an extended period, deposition of HAPS could accumulate in soil and sediments to a condition where they may contribute to an unacceptable level of exposure. How is the accumulation of HAPs in ecosystem compartments over a period of extended emissions considered?

Charge Question 3: Does the SAB find that the assumptions for human fishing behavior used in the refined fisher scenario, the assumptions about PB-HAP deposition to lakes, and the assumptions on the ability of ponds and lakes to sustain populations of fish are appropriate?

I am generally supportive of the fishing response. However, I have a number of concerns. From my experience there is considerable heterogeneity in lakes. I have concerns with the universality of some of the assumptions invoked for the analysis. For example, 21% of the fish biomass as piscivores; benthic fish accounting for 17.5% and pelagic fish accounting for 3.5% of total fish biomass; humans consume 50:50% from benthic and pelagic piscivores, note some people eat pan fish; total fish biomass is 40 g fish ww/m^2. I assume these assumptions have a wide range of occurrences. Can EPA do a sensitivity analysis to investigate the sensitivity the estimates of exposure are to these assumptions?

Charge Question 6: Does the SAB find that the environmental risk screening approach is appropriate for identifying facilities whose PB-HAP emissions may have the potential to cause adverse environmental effects? Specifically, does the SAB find that the pollutants (Section 4.2.1), ecological assessment endpoints (Section 4.2.2), and benchmarks (Section 4.3) that are included in the environmental risk screen are appropriate? Does the SAB have specific suggestions for improvement with regard to any aspect of this environmental risk screening methodology?

In general I am supportive of this approach for environmental screening, although I have some questions which I indicated above in my response to charge question 1. Moreover, I am concerned that the analysis may not be adequate to protect against mercury deposition because of the strong bioaccumulation of methyl mercury.

P. 65 It might be possible to examine HCl effects by evaluating the concentrations of chloride contributing to loss of acid neutralizing capacity or soil percent base saturation. This type of modeling in routinely done in acidification modeling.

p. 69, Table 4-1. The water quality and soil criteria for mercury are very high. This is particularly true for water where concentrations are typically ng/L. To give an example, the sediment clean-up values for Onondaga Lake, NY, a mercury contaminated site are 2.2 µg/g for probable effective concentration based on macroinvertebrate toxicity testing and 0.8 µg/g for bioaccumulation based sediment quality.

p. 77 In addition to effects level criteria for top predator, I have seen criteria established for bioaccumulation effects, such as the example I gave above for Onondaga Lake, NY and to protect the health of prey species.

Table 4-3 How does one extrapolate from inorganic mercury to methyl mercury. Most wildlife effects are due to bioaccumulation of methyl mercury. Does TRIM. FaTE simulate the conversion of ionic mercury to methylmercury.

Other comments

Section 3-4, p 59. Isn't urban deposition of HAPS much greater that rural values? This would increase the overall exposure of an urban gardener.

P 54, line 12 What is the time series of meteorology over which the plume analysis is conducted? Is this over multiple years? A single year? Could this be clarified.