UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

September 13, 2018

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-18-003

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Review of EPA's draft technical report entitled *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*

Dear Acting Administrator Wheeler:

The Science Advisory Board was asked by EPA's Office of Air Quality Planning and Standards to review the EPA draft document titled, *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (May 2017). The draft RTR methods document describes the 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.

The SAB Risk and Technology Review Methods Review Panel deliberated on the charge questions specific to the Agency's draft RTR methods document during a June 29-30, 2017, face-to-face meeting and discussed the SAB panel's draft report in a subsequent conference call on December 5, 2017. The charge questions focused on eight topics within the Agency's draft RTR methods document, including: a three-tiered multipathway screening approach used in the RTR screening analyses; a risk equivalency factor methodology; fishing, lake and pond assumptions; lake data, plume rise, and meteorological data; a gardener scenario; environmental risk screening methodology; inhalation risk assessment enhancements; and the census block receptor check tool. The enclosed report provides the SAB's consensus advice and recommendations in response to the charge questions. This letter briefly conveys the major findings.

The SAB commends the EPA on the technical quality of the draft RTR document and the effort it has put into developing the residual risk screening methodology. The SAB finds that the overall methodology and specifically the revisions since 2009 are for the most part appropriate and improve the assessment capabilities; opportunities for improvement are documented in the SAB's report. The SAB concludes that the EPA's approach has the potential to achieve the Agency's goal to rapidly and effectively screen facilities, and to focus EPA time and resources on sites of most concern from a public health point of view.

Insufficient detail was provided in the Agency's draft RTR methods document for the SAB to assess the overall operational effectiveness of the screening methodology such as how many facilities are screened out by each of the three tiers. Some data were provided later by the EPA that did help the SAB to understand the screening efficacy. The SAB recommends the EPA compile summaries of RTR analyses applied in regulatory activities for inclusion in future RTR methodology report documents. Furthermore, in future screening analyses the EPA should compare, for specific facilities, the screening model output to field data where available. These "ground truthing" studies should be included in the next RTR methods document and provided to future reviewers for consideration.

Concerning the lifetime average daily dose (LADD) estimates when calculating exposure equivalency factors, EPA's empirical correlation is a logical step in creating the read-across approach used by the Agency. However, the read-across approach for environmental fate is less well-tested and accepted and thus deserves further consideration[1]. The SAB notes that this read-across extrapolation of environmental fate could be refined and has identified two options for the EPA to consider for improving the LADD estimates.

The SAB finds that the inclusion of the domestic gardener scenario is appropriate, though an evaluation of how many people this applies to should be conducted to determine the efficacy of the addition. The accuracy of dispersion and deposition results from the TRIM.FaTE model should be evaluated by comparing them with the results from a more technically robust dispersion model, such as AERMOD. In addition, while incorporation of turbulence in determining urban/rural selection in dispersion modeling is appropriate, the SAB recommends a different approach suggesting a more physically-based model such as AERMOD and the use of meteorological reanalysis data for both surface-air and upper-air wind speeds. Finally, the SAB finds that the EPA's reliance on census-block centroid locations as surrogates for where people live might not always be sufficient to ensure that receptors are representative of residential areas near facilities, and thus the SAB recommends that additional, reproducible methods should be evaluated.

The SAB recommends the EPA explore a transition for its screening methodology from using single-point estimates of uncertain input values to using distributions for these values. Probabilistic analyses combining the effects of distributions of multiple input values would result in a coherent analysis from which arithmetic means and "conservative fractiles" (e.g., a 90^{th} percentile) could be derived. While in the interim sensitivity analyses on uncertain input values could be performed, the shift to a probabilistic analysis framework would provide a more robust foundation for the screening methodology in higher tiers.

[1] Physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to as source substance(s), by interpolation to other substances in the group, referred to as target substance(s). This approach is called "read-across." (https://echa.europa.eu/documents/10162/13628/raaf_en.pdf)

In summary, the SAB supports the framework and direction of refinements EPA has been making to the screening methodology for the residual risk portion of RTR analyses. The SAB appreciates the opportunity to provide the EPA with advice on this important subject. We look forward to receiving the EPA's response.

Sincerely,

/Signed/	***/Signed/***
Dr. Michael Honeycutt, Chair Science Advisory Board	Dr. Jay Turner, Chair Risk and Technology Review Methods Review Panel

Enclosure

NOTICE

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Science Advisory Board

OH

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Dr. Bryan J. Bloomer, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

1. TABLE OF CONTENTS

Acronyms and Abbreviations

AERMOD	AMS/EPA Regulatory [Dispersion] Model
AMS	American Meteorological Society
ATSDR	Agency for Toxic Substances and Disease Registry minimum risk levels
AEGL	Acute Exposure Guidelines Limits
ANPRM	Advanced Notice of Proposed Rulemaking
BaP	benzo(a)pyrene
CalEPA	California Environmental Protection Agency
EEF	exposure equivalency factor
ERA	Ecological Risk Assessment
ERPG	Emergency Response Planning Guidelines
HAP	Hazardous Air Pollutant
K_{ow}	the *n*-octanol/water partition coefficient
IRIS	Integrated Risk Assessment System
LADD	lifetime average daily dose
MACT	Maximum Achievable Control Technology
MTBE	Methyl Tertiary Butyl Ether
NATA	National Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standard for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Testing
NPRM	Notice of Proposed Rulemaking
NWS	National Weather Service
OAQPS	Office of Air Quality Planning and Standards
OPP	Office of Pesticide Programs
OSHA	Occupational Safety and Health Administration
OEHHA	Office of Environmental Health Hazard Assessment
PAH	Polycyclic Aromatic Hydrocarbon
PB-HAP	Persistent Bioaccumulative - Hazardous Air Pollutant
POM	Polycyclic Organic Matter
REF	risk equivalency factor
RTR	Risk and Technology Review
SAB	Science Advisory Board
TEF	toxicity equivalency factor
TEQ	Toxic Equivalents
TRIM.FaTE	Total Risk Integrated Methodology - Fate, Transport and Ecological Exposure
UCL	Upper Confidence Limit
USDA	US Department of Agriculture
USGS	US Geological Survey

1. EXECUTIVE SUMMARY

This report was prepared by the U.S. EPA Science Advisory Board (SAB.) The Board convened the Risk and Technology Review (RTR) Methods Review Panel for initial deliberations in response to a request by EPA's Office of Air Quality Planning and Standards (OAQPS) to review their draft document entitled, "*Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (U.S. EPA 2017). This document (hereinafter referred to as the "Agency's draft RTR methods document") describes portions of the methods used to assess "residual risk" i.e., the potential risks remaining after application of maximum achievable control technology (MACT) pursuant to the National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations.

Screening methodologies are used to quickly identify those facilities in a source category that have little potential for human health multipathway or environmental risk, while also identifying those facilities where a refined multipathway or environmental risk assessment may be needed. The Agency's draft RTR methods document describes several improvements to the screening methods.

The SAB reviewed the draft RTR methods document as requested by considering eight charge questions posed by the EPA (See Appendix A). The SAB provides comments on the RTR screening methods and does not address the regulatory implications of the methods or the document. The SAB also notes that no methods were submitted for review regarding the technology portion of the RTR analysis called for by the NESHAP regulations, nor were charge questions posed regarding the technology review methods to be applied by the EPA.

The SAB RTR Methods Review Panel deliberated on responses to the charge questions specific to the Agency's draft RTR methods document during a face-to-face meeting on June 29-30, 2017, and discussed its draft report in a subsequent conference call on December 5, 2017. The Chartered SAB conducted a quality review of this document on May 31, 2018. The charge questions focused on eight topics within the Agency's draft RTR methods document, including: *the three-tiered multipathway screening approach used in the RTR analyses; the risk equivalency factor methodology; fishing, lake and pond assumptions; lake data, plume rise, and meteorological data; the gardener scenario; environmental risk screening methodology; inhalation risk assessment enhancements; and the census block receptor check tool.*

This Executive Summary highlights the SAB's major findings and recommendations. The SAB commends the EPA on the technical quality of the draft RTR methods document and the thought and effort it has put into developing the residual risk screening methodology. The SAB finds that the overall methodology and specifically the revisions since 2009, are reasonable and should improve the EPA's assessment capabilities. The comments and recommendations offered below are intended to assist EPA staff as they seek to improve their RTR assessments going forward and are not meant to detract from the screening and assessment efforts to date.

The SAB agrees that the three-tier multipathway risk screening approach, starting with health protective parameters and moving to more site-specific parameters in later tiers, is reasonable and logical. The SAB finds the expansion of the endpoints for the environmental risk screen is reasonable and the benchmarks and use of a tiered screening system are justified. Overall, the screening methodology has the potential to achieve the EPA's goal to quickly screen facilities, and to focus Agency time and resources on sites of most concern from a public health point of view.

The SAB recommends that future RTR methods documents be written for a primary audience envisioned as a risk assessor trying to reproduce the results of an EPA RTR risk assessment screening, rather than for the audience of peer reviewers.

The SAB finds summary information about overall performance of the methods and case studies to be missing from the report or inadequate for a comprehensive assessment of the methods described. For example, the SAB could not assess the overall operational effectiveness of the screening methods, such as how many facilities are screened out compared to those facilities passed on for more detailed analysis. The SAB very strongly recommends the EPA compile summaries of RTR analyses applied in regulatory activities and include the summaries in future RTR documents for review by the Board. In addition, analysis of the results by source category may indicate that some types of facilities screen out earlier than others and it may point out risk drivers, sensitive parameters and key features that could be refined to improve the screening analysis for particular source categories in the future.

In future screening analyses the EPA should compare, for specific facilities, the screening model output with field data, where available. For example, field measurement data on relevant persistent bioaccumulative hazardous air pollutants (PB-HAPs) in atmospheric deposition, soil, water, and fish could be used to validate key screening model outputs, especially in the Tier 3 evaluation. These "ground truth" studies must be included in the next RTR methods document and provided to future SAB reviewers for consideration.

Data quality considerations are important in RTR assessments. Experience has shown that significant errors can occur in RTR input data, which in turn, can skew risk results, sometimes by material, policy-relevant margins. Accurate input data are the bedrock foundation on which all RTR risk analyses build. The SAB recognizes EPA's past efforts to ensure RTR input data accuracy, and strongly supports and encourages such efforts. Building on the substantial efforts that EPA staff have already made, EPA could further develop and expand its affirmative efforts to ensure RTR input data accuracy. The possibility of such errors and their policy implications should continue to be considered when conducting RTR risk analyses and interpreting results.

The SAB recommends the EPA examine refinements to the tiered screening methodology by conducting sensitivity studies to identify the key input values that drive the risk estimates. EPA also should evaluate the use of probabilistic analyses to estimate more accurately the overall risks. In cases where these input values are uncertain but appropriate, distributions for these parameters could be constructed; probabilistic analysis would provide a more robust foundation for the screening methodology.

Regarding the risk equivalency factor (REF) calculation, the SAB supports the toxicity equivalency factor (TEF) read-across approach as it is well accepted for dioxins and carcinogenic polycyclic aromatic hydrocarbons (PAHs). For the exposure equivalency factor (EEF) estimate, the read-across approach, for environmental fate and transport, is not as well tested and thus deserves further consideration. EPA's empirical correlation between the *n*-octanol/water partition coefficient (K_{ow}) and lifetime average daily dose (LADD) for chemicals with sufficient data is a logical step in creating the read-across approach used by the EPA. However, K_{ow} is an imperfect predictor of LADD and incorporation of other factors (e.g., environmental persistence and molecular weight) may improve the estimates. The SAB finds this read-across extrapolation approach could be refined and has identified two options for the EPA to consider for improving the EEF estimates.

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 PAHs not currently identified as carcinogens; and (b) documentation of the methods for the EEF derivation.

The SAB is generally supportive of the assumptions used for human fishing behavior in the refined fishing scenario and offers several specific suggestions for improving the data used, the model versions used, and how to document studies used by the EPA for the data and modeling methods.

Tier 3 screening introduces refinements to the treatment of air pollutant dispersion and deposition. EPA should consider the use of plume-rise models other than those described in the Agency's draft RTR methods document and could test and demonstrate the reliability of plume rise adjustments. The accuracy of dispersion and deposition results from the TRIM.FaTE model should be evaluated by comparing them with the results from a more technically robust dispersion model, such as AERMOD. The SAB suggests EPA evaluate the selection of urban vs. rural terrain in the inhalation risk assessments by comparing TRIM.FaTE-derived screening results to those calculated by a more physically-based model such as the regularly updated AERMOD. For this and other air dispersion and transport modeling, the SAB recommends that EPA consider the use of meteorological reanalysis data for both surface-air and upper-air wind speeds.

The SAB agrees that the proposed gardener scenario is an appropriate addition to both Tier 2 and Tier 3 screening evaluation. However, it is important to distinguish between the gardener and the subsistence farmer. The gardener scenario improves the characterization of potential risk in both rural and urban environments for those who take part in this activity, however the SAB urges the EPA to gather data characterizing the population engaged in this activity and the primary exposure routes in order to evaluate the efficacy of this scenario.

The Agency should consult with colleagues across the EPA who have data and models for addressing parameters used in the screening analysis. For example, the SAB understands the Agency has data or models available for parameters such as lake outflow, chemical runoff and erosion.

The SAB found the methodology for identifying the pollutants to be included in the environmental risk screening activities are clearly stated and the criteria used to prioritize the chemicals are found to be appropriate. The SAB is concerned that selenium is not included as a chemical to screen and recommends that it be added in future RTR screening analyses.

The SAB agrees that characterizing the terrain as urban versus rural and incorporating the effects of turbulence as a dispersion modeling input is appropriate. This refinement has significant value because it avoids the overly conservative assumption of applying the "rural" assumption to all facilities. However, the SAB disagrees with the Agency's draft RTR methods document on the procedure of choice and recommends using a land use-based procedure utilizing national land cover data (NLCD).

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. Overall, the SAB finds that, while the method's reliance on census block centroid locations may in some cases be sufficient for screening, care must be taken that receptors are well-placed to be representative of residential areas near the facilities. To facilitate tool transparency and results reproducibility, EPA could develop protocols to enable risk assessors to exercise their professional judgment in verifying the tool-based receptor placements and document the decision process for placement (e.g., using Google Earth imagery and preliminary risk calculations) so as to be reproducible by independent expert analysts.

In summary, the SAB supports the framework and direction of refinements EPA has been making to the screening methodology for the residual risk portion of RTR analyses. In many cases, the SAB supports the methodological details used by the EPA; and in other cases, the SAB recommends considering refinements or alternative approaches.

By the EPA's accounting, provided in response to inquiry by the SAB, for the five most recent RTR analyses conducted prior to June 2017, Tier 1 on average screened out 30% of the affected facilities, and the Tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively, of the affected facilities. This demonstrates a commitment to effectively manage EPA resources and focus attention on the subset of facilities that are not deemed low-risk based on the screening analysis. However, insufficient information was provided in the RTR methodology report for the SAB to evaluate the overall efficacy of the EPA's methods. EPA's multi-tiered risk screening approach appears designed intending that: (a) high-risk facilities are not prematurely screened out (with adverse public health or environmental implications) and (b) low-risk facilities are not unnecessarily retained for more detailed analysis (with adverse EPA resource implications). The SAB strongly calls for data to be developed and presented in future method reports that indicate how many facilities may be screened out prematurely and how many may be passed on to a full-scale risk assessment that should have been screened out in the screening analysis.

2. INTRODUCTION

EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the Science Advisory Board (SAB) review the draft document, "*Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (U.S. EPA 2017). This document (hereinafter referred to as the "Agency's draft RTR methods document") describes the EPA's recent and proposed refinements to the screening methods for assessing "residual risk" i.e., the risks remaining after application of maximum achievable control technology (MACT) under Title I of the Clean Air Act (CAA).

The CAA establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAPs) from stationary sources. In the first stage, the CAA requires EPA to develop technology-based standards connected to MACT for categories of industrial sources. EPA must review each MACT standard at least every eight years and revise them as necessary. This is the technology review portion of RTR. In the second stage of the process, EPA is required to assess the health and environmental risks that remain after MACT has been applied. EPA must develop standards to address these remaining potential risks if necessary to protect the public health with an ample margin of safety or to prevent adverse environmental effects. This second stage of the RTR is known as the residual risk review and must be completed within eight years of promulgation of the initial MACT standards for each source category.

The EPA, in order to streamline and standardize the residual risk review for the large number of affected source categories, has developed a process by which it: (1) conducts a risk assessment using currently available source and emissions data; (2) requests public comment on the source and emissions data, along with preliminary risk assessment results, through an Advance Notice of Proposed Rule Making (ANPRM); (3) addresses comments received on the ANPRM; and (4) revises the risk assessment as needed. The results of the revised risk assessment are intended to support proposals and promulgation of technology- and risk-based regulatory decisions through a transparent, science based, notice-and-comment rulemaking process.

The Agency's draft RTR methods document describes revisions to the screening methods used when conducting the risk portion of Risk and Technology Review assessments. These assessments evaluate the effects of industrial HAPs emissions on public health and the environment. Screening methods are used to quickly identify, for a particular RTR source category, those facilities that have little potential for human health risk via multipathway exposure or little potential for environmental risk, while also identifying those facilities where a refined risk assessment may be needed.

Previous internal EPA and external peer review panels have reviewed aspects of the RTR methodology, as documented in the following reports:

1) The *Residual Risk Report to Congress* (U.S. EPA 1999), a document describing the EPA's overall analytical and policy approach to evaluating residual risk in the context of setting NESHAP standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methods were described in

this report, although individual elements have been refined over the subsequent two decades.

2) Individual residual risk assessments – several internal peer reviews and one external peer review were conducted on risk assessments for individual source categories, including Coke Ovens (U.S. EPA 2018a), Perchloroethylene Dry Cleaning (U.S. EPA 2018b), and Halogenated Solvent Cleaners (downloadable from: U.S. EPA 2018c). Each of these assessments used emission estimates from the National Emissions Inventory (NEI), human exposure modeling at the census block level, dose-response methodologies, and risk characterization like those for the ongoing and planned RTR assessments.
3) The National Air Toxics Assessment, or NATA, for 1996 was peer-reviewed by the SAB in 2001-2002 (U.S. EPA SAB 2001). NATA 1996 was a comprehensive and cumulative risk assessment designed to include all mobile sources, small and large industrial sources, and background contributions to air toxics. Because of significant uncertainties, the SAB did not believe that it was appropriate for regulatory purposes. For example, the 1996 assessment had census block-level data resolution available, but the analysis was performed at the census tract level. This approach was refined in subsequent assessments.
4) The AMS/EPA Regulatory [Dispersion] Model (AERMOD), a source-to-receptor air quality dispersion model, was the subject of significant interagency cooperation and peer review. It is now EPA's preferred local-scale air dispersion model for industrial sources of air pollution (U.S. EPA 2018d).
5) The individual dose-response values used in RTR assessments have been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA; and the Agency for Toxic Substances and Disease Registry, or ATSDR). EPA proposes to select dose-response values for long-term exposures from these sources in the same priority order it used for NATA (i.e., IRIS, then ATSDR, then CalEPA). For acute exposure toxicity, EPA arrays several indices without prioritization; this is a source of potentially significant, yet usually unquantified, uncertainty. (IRIS - U.S. EPA 2018e, ATSDR - ATSDR 2018, CalEPA -CalEPA 2018)
6) An earlier peer review of multipathway risk assessment methodologies was conducted by the SAB in 2000 (U.S. EPA SAB 2000).
7) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by the SAB in 2006. The final SAB letter to Administrator Johnson transmitted the Board's comments (U.S. EPA SAB 2007).
8) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009 (U.S. EPA SAB 2010). This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing.

The focus of this review of the Agency's RTR methods document is on several updates and enhancements of the previous versions that were reviewed as documented above. The most important revisions and enhancements since the last SAB review include the following:

- a tiered multipathway screening methodology that determines whether the potential for multipathway human health risk from persistent and bioaccumulative HAP (PB-HAP) emitted from RTR source categories is low or whether more analysis is needed;

- a tiered environmental screening methodology that determines whether the potential exists for adverse ecological effects from PB-HAP and the acid gases hydrogen chloride (HCl) and hydrogen fluoride (HF) emitted from RTR source categories;
- the potential addition to the screening methodology of a new multipathway exposure scenario to estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables; and
- enhancements to the previously reviewed inhalation risk screening methodology that allow more accurate modeling of air concentrations where populations reside and better characterization of air dispersion near sources.

The SAB was asked to review the current draft RTR methods document by considering eight charge questions posed by the EPA. The SAB provided comments on the RTR methods and did not address the regulatory implications of the method or the report. The SAB Risk and Technology Review (RTR) Methods Review Panel met in a public meeting on June 29 – 30, 2017 in Arlington, VA, to review the Agency's draft RTR method document. The SAB Panel held a subsequent teleconference on December 5, 2017, to discuss its draft advisory report. The Chartered SAB conducted a quality review of this report on May 31, 2018. The specific charge questions to the SAB are presented in the next chapter, along with the SAB's responses.

3. RESPONSE TO INDIVIDUAL CHARGE QUESTIONS

3.1 The Three-Tiered Multipathway Screening Approach

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?

RTR risk assessments provide the basis for decision making on whether a more stringent standard is necessary to protect human health and the environment after implementation of a NESHAP for a specific source category. The risk assessment process is both time and resource intensive. Therefore, EPA first screens affected facilities to determine whether a full-scale facility-specific risk assessment is warranted. Since the 2009 SAB review of RTR methods, the EPA has developed a three-tiered multipathway screening approach that progressively replaces health-protective default assumptions with location and facility specific data. The goal is to "screen out" minimal risk facilities such that only potentially high-risk facilities remain in the pool for further analysis.

EPA's screening methodology for ingestion risks uses a multipathway, tiered approach. Models are used to simulate the transport and fate of HAPs emitted from specific facilities in the source category being assessed. Modeling outputs include estimates of contaminants in the environment and estimates of human health risks primarily from the ingestion of HAPs from food products such as vegetables, fruit, meat, and fish because the focus of this tiered screening is on persistent and bioaccumulative toxicants.

The SAB agrees that the three-tier multipathway risk screening approach, starting with generic health protective parameters and moving to more site-specific and realistic parameters in later tiers, is appropriate. Its general structure is consistent with a long history of EPA multi-tiered risk screening approaches designed with the intent that: (a) high-risk facilities are not prematurely screened out (with adverse public health or environmental implications) and (b) low-risk facilities are not unnecessarily retained for more detailed analysis (with adverse EPA resource implications). While the SAB finds the overall approach is appropriate and has the potential to achieve the EPA's goals, as noted below the overall effectiveness is not clear. EPA should evaluate the current effectiveness and refinements to improve effectiveness.

Based on the information presented in the draft RTR methods document, the effectiveness of the screening methodology could not be confirmed. The SAB strongly calls for data to be developed and presented in future method reports that indicate how many facilities may be screened out prematurely and how many may be passed on to a full-scale risk assessment that should have been screened out in the screening analysis.

Screening efficacy could be examined in two ways. First, the operational effectiveness could be evaluated by reviewing the number of facilities screened out by each tier. While this information was not provided in the Agency's draft RTR methods document, EPA subsequently reported that for the five most-recent RTR analyses conducted (at the time of the EPA's correspondence on November 9, 2017), Tier 1 on average screened out 30% of the affected facilities, and the Tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively, of the affected facilities. More information included in the report would have been useful when assessing the appropriateness of modeling inputs and assumptions. An analysis of the tier-specific screening efficacy should be conducted for each source category (i.e., an examination of prior RTRs which used the current approach to screening) to assess whether some types of industrial facilities screen out earlier than others. This analysis may point out the risk drivers, sensitive parameters and key features that could be refined to conduct better screening analysis for particular source categories in going forward. Second, the best way to evaluate the three-tiered approach in a scientific manner is to "ground-truth" the evaluations, using monitoring data from either new sites or previously evaluated sites. This type of validation would require focused and deliberate study, yet it would represent an improvement in the understanding of screening procedures. For example, available monitoring data on PB-HAPs in atmospheric deposition, soil, water, and fish could be used to examine the effectiveness of higher-tiered screening and in particular to validate key points in the Tier 3 evaluation.

EPA's tiered approach is geared towards protecting the most highly exposed subpopulations – combined subsistence fishers and farmers and their children who also ingest soil. The first tier is intended to be quite health protective and SAB concurs that it is conservative. Page 15 of the Agency's draft RTR methods document highlights some of the more health-protective assumptions in the Tier 1 screening scenario. However, many assumptions are not transparent in the Agency's draft RTR methods document, making it impossible to assess if there are opportunities for refinement of those assumptions. For example, EPA should list the key assumptions used for the watershed characteristics that enhance chemical loading to the lake and farm via erosion and runoff e.g., it is not clear how the chemical is loaded into the lake and the assumptions for the volume of water transporting the chemical into the lake. This is a particularly relevant example because the scenario does not change across the tiers and there might be opportunities for refinements.

There is concern about the specific values selected for the modeling parameters, both individually and in combination. The use of multiple high-end health protective parameters can result in an excessive overestimate of potential risk. While each health-protective assumption on its own may seem reasonable, combining or overlaying multiple health protective assumptions can lead to more conservatism than is intended. An unintentionally high and unnecessary degree of conservatism likely renders the tiered risk screening ineffective, or at best inefficient. EPA should consider possible refinements to Tier 1 if the overestimation of risk is such that obviously low-risk sites are not screened out.

The SAB recommends the EPA examine refinements to the tiered screening methodology by conducting sensitivity studies to identify the key input values that drive the risk estimates. This could be used to refine Tier 1 if desired and is particularly relevant to Tiers 2 and 3. As one example, the EPA could conduct a sensitivity analysis on the impact of runoff assumptions on modeled human health risk and consider refining the health-protective Tier 1 runoff parameters as the screen moves to Tier 2 and to Tier 3. As the EPA conducts these evaluations, it should have the flexibility to adjust its methods and the parameters as needed to ensure health-protective yet efficient RTR screening occurs in future RTR screening analyses.

EPA should evaluate the use of probabilistic analyses, perhaps initially through case studies on Tiers 2 and 3 analyses, to more accurately estimate overall risks. As previously stated, sensitivity analyses can be used to identify key input values that drive the risk estimates. In cases where these input values are also uncertain, probabilistic analysis would provide a more robust foundation for the screening methodology. This would require assessing whether enough data are available to construct distributions for the input parameters. If so, then probabilistic analysis combining the effects of distributions of multiple input values would result in a coherent analysis from which arithmetic means and operationally-defined "conservative fractiles" (e.g. a 90th percentile) could be derived.

Overarching data quality considerations are important in RTR assessments. Errors can occur in RTR input data which in turn can skew risk results, sometimes by material, policy-relevant margins. Data errors can be caused by such factors as reporting mistakes by individual facilities and undetected, incorrect information in publicly-available national, regional, and local emission inventories. The SAB recognizes the fundamental importance of accurate input data as a bedrock foundation on which all RTR risk analyses build. The SAB recognizes EPA's past efforts to ensure RTR input data accuracy, and strongly supports and encourages such efforts. Building on the substantial efforts that EPA staff have already made, EPA could further develop and expand its affirmative efforts to ensure RTR input data accuracy. Possible approaches to reducing such errors were discussed during the panel's public deliberations and are documented in the public records of the meetings available on the EPA website (EPA 2018f). The possibility of such errors and their policy implications should continue to be considered when conducting RTR risk analyses and interpreting results.

Additional comments and recommendations are as follows.

- If EPA seeks to further refine the Tier 1 screening of low-risk facilities, it might reconsider the current approach of combining exposures for farming and fishing on top of other conservative assumptions regarding weather conditions, deposition and runoff. It is unlikely that the same person consumes <u>all</u> food categories from media located close to the facility and these media receive the conservative-estimate high-end chemical loading rates day after day.
- Although there are refinements to the air modeling at Tiers 2 and 3, there is no comparable refinement of chemical runoff and erosion from the watershed. EPA does not provide any information on parameters and assumptions made (including the pond scenario) and thus the SAB cannot provide detailed comments on potential refinements to these models.
- TRIM.FaTE (U.S. EPA 2002) is used to model air dispersion. EPA should indicate if this model has been updated since 2002, and why EPA chose this model over AERMOD, which has been continuously improved and updated many times over the years (as recently as January 2017). It may be useful for EPA to compare estimates based on TRIM.FaTE and AERMOD for a range of representative scenarios.
- As discussed in more detail in the response to Charge Question 3, there is a complicated reasoning underlying the Tier 2 sustainable fishing scenario. Perhaps

EPA found it necessary to introduce such details at Tier 2 to be able to screen out low-risk facilities. For the purposes of Tier 2, however, it seems that simpler worst-case assumptions could be made that simplify the approach. The SAB recommends the EPA consider other data available to make more realistic assumptions, such as the most recent National Health and Nutrition Examination Survey (NHANES CDC 2018.), to estimate fish consumption.

- Many of the pathways are related to those used by the EPA Office of Pesticide Programs (OPP), which are based on U. S. Department of Agriculture (USDA) Cropland Data Layer and more recent (2005-2010) NHANES dietary consumption data. These could be used to inform EPA's RTR screening approaches[2]
- Regarding some of the individual parameters, from the documentation provided it wasn't clear whether the breastfeeding exposure or other early life pathways would adequately cover these sensitive early life stages. The potential impact of seasonal changes in food-sourcing should also be considered although it was recognized that fishing and gardening/farming can be year-round activities in certain parts of the country.
- The focus only on cancer risk for dioxins and benzo[a]pyrene may underestimate early life (e.g., breastfeeding) risks given these are short-term exposures whose lifetime average daily dose (LADD) will be diluted by the rest of the lifetime at lower exposure. Table 3.2 indicates that non-cancer endpoints are "not critical" for these chemical classes; this is a pre-judgement that should be further explored, especially for early life exposures. The SAB notes that benzo[a]pyrene has a very recent RfD on IRIS that is based upon an early life developmental effect (U.S. EPA 2018g).
- Several polycyclic aromatic hydrocarbons (PAHs) with toxicity equivalency factors (TEF) are not generally considered carcinogens (e.g., pyrene, phenanthrene, fluorene, fluoranthene, and acenaphthalene). These compounds do not appear on the lists of relative potency factors used by EPA (U.S. EPA, 1993) nor are they presented in lists published elsewhere (e.g., Nisbet and Lagoy 1992). These early 1990s references are still relevant as demonstrated by EPA's 2017 IRIS toxicological review for benzo(a)pyrene which refers to the EPA's 1993 guidance as the source of PAH relative potency factors (U.S. EPA 2018h). In addition, the PAHs in question are not listed as carcinogenic by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services. The TEF approach for pyrene, phenanthrene, fluorene, fluoranthene, acenaphthalene and several other PAHs should be reconsidered.
- The draft RTR methods document should be modified to be more explicit about the decision-making on transitioning from Tier 1 to Tier 2, and from Tier 2 to Tier 3, particularly with regards to evaluating the potential risks associated with multiple chemicals and combining hazard quotients and risks. In addition, the basis for the inclusion and exclusion of particular chemicals, for example lead, should be more clearly stated.
- Page 16 of the draft RTR methods document indicates that "dermal absorption of originally airborne chemicals similarly has been shown to be a relatively minor

[2] https://websoilsurvey.sc.egov.usda.gov/App/HomePage.htm; https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Ag_Atlas_Maps/; https://www.epa.gov/sites/production/files/2015-09/documents/deem-user-guide-sep30-14.pdf); https://www.epa.gov/sites/production/files/2016-05/documents/public_webinar_overview_of_the_draft_bes_final.pdf

exposure pathway compared with other pathways" and cites one report from 2000 and another from 2006, to support the statement. The EPA should investigate whether the evidence still supports that conclusion and applies to all classes of chemicals. More recently, several studies have suggested that dermal absorption of certain classes of chemicals in indoor air can contribute significantly to a person's overall dose (Weschler and Nazaroff, 2012, 2014; Morrison et al., 2016).

- The SAB supports the EPA's decision to separate subsistence farmers and subsistence fishers in Tier 2.
- The SAB notes that by conducting the analysis on a chemical-by-chemical basis, limited by law to the industrial category under RTR evaluation, multiple sources of a chemical emitted nearby from other industrial source categories may contribute to cumulative effects and chemical interactions because of multiple exposures. The cumulative risk may be missed by the human health risk screening conducted following the RTR method being reviewed.

3.2 Risk Equivalency Factor Methodology

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?

Previously the RTR screening methods did not account for differences in environmental transport and fate among POM or dioxin congeners in the Tier 1 screening approach. All POM congeners were assumed to be transported, partition, and degrade in the environment identical to benzo(a)pyrene (BaP), and all dioxins were assumed to exhibit the same transport and fate as 2,3,7,8-TCDD. Since 2009 when the RTR Methodology was last reviewed by the SAB, the EPA has significantly refined its approach. Section 3.1.2 of the Agency's draft RTR methods document describes a new risk equivalency factor (REF) methodology that includes an exposure-equivalency factor (EEF) to reflect an individual chemical's transport and fate relative to the index chemical for each group (i.e., BaP for POM and 2,3,7,8-TCDD for dioxin).

The REF methodology has been incorporated as a screening tool into the residual risk assessment of stationary sources. It grapples with a common problem when dealing with complex mixtures – the evaluation of components with poorly characterized environmental fate and toxic effects. The SAB appreciates that when data gaps preclude inclusion of a chemical component of POM in a risk assessment, this component is often assumed to contribute zero exposure and risk. Rather than create such an underestimation, EPA has provided a screening methodology to fill such data gaps and thus include the full array of targeted POM constituents. In general, the SAB finds the overall approach to potentially be appropriate with more work needed to address concerns as described below.

The REF methodology consists of two read-across approaches[3] – one to handle toxicology data gaps, and the other to handle information gaps regarding environmental transport and

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[3] Physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to as source substance(s), by interpolation to other substances in the group, referred to as target substance(s). This approach is called "read-across." (https://echa.europa.eu/documents/10162/13628/raaf_en.pdf)

fate. The SAB agrees with the toxicity equivalency factor (TEF) approach as it is well accepted for dioxins and carcinogenic PAHs. The SAB has not checked all the tabulated values for representativeness but notes that some of the PAHs given TEF factors by EPA are not typically considered to be carcinogenic; this was discussed in the SAB's response to Charge Question 1. The selection of TEFs for these and other PAHs is not provided in the Agency's draft RTR methods document and should be documented with references in Table 3.4.

The read-across approach for environmental fate is less well tested and accepted and thus deserves further consideration. EPA's proposed EEF is based upon a fundamental chemical property – K_{ow}. This property helps determine certain aspects of environmental fate such as uptake into fish, beef and dairy, but there are numerous other fate behaviors which it does not predict such as metabolism, biodegradation, environmental half-life and several types of phase transitions and partitioning. Thus, it is perhaps overly optimistic to expect K_{ow} by itself to have high concordance with exposure dose.

EPA's empirical correlation between K_{ow} and LADD for chemicals with sufficient data (RTR methods report Figure 3.2. U.S. EPA 2017) is a logical step in creating the read-across approach. However, as suggested above, K_{ow} is an imperfect predictor of LADD. Figure 3.2 shows the relationship between K_{ow} and LADD for 14 POM analytes for which there are more complete data. There is considerable variability around the regression line in Fig 3.2; this variability is currently unexplored but may arise from uncertainty and variability in the underlying parameters that influence the LADD including not only K_{ow} but also intermedia partition coefficients, molecular weight, half-life, potential for biodegradation, etc. The variability around the regression line is up to two orders of magnitude and thus the calculated EEF may substantially underestimate the LADD for some undefined members of data-poor chemical classes.

The SAB finds this read-across extrapolation of environmental fate could benefit from a refined approach and has identified two options for improving the EEF estimate as follows.

- Conduct further statistical evaluation of the relationship between K_{ow} and LADD to generate an upper bound on the regression slope and then apply this to derive EEFs for data poor chemicals.
- Conduct further evaluation of the underlying transport and fate parameters to develop distributions for each influential parameter and then perform a probabilistic analysis that replaces the Fig 3.2 regression slope; EPA can then make a transparent choice of which percentile of the distribution of LADDs for a given K_{ow} (and/or additional parameters) will be used in evaluating exposure and risk for data-poor POMs.

The SAB also finds the current documentation of key parameter inputs to the fate, transport and bioaccumulation model for PB-HAPs is not adequately described. The range of potential values and key citations should be presented in an appendix for all the modeled PB-HAPs. The document states that the EEF will change based upon environmental and geospatial conditions (e.g., Page 19, paragraph 1) but examples of this dynamic relationship are not provided, which further precludes a full review. For example, how are the effects of age/weathering incorporated to account for the loss of lighter dioxin congeners over time or with distance?

The SAB notes that in Table 3.4, the products of the EEF and TEF values do not always equal the corresponding REF. Perhaps rounding prior to the multiplication causes these differences. Whatever the reason, the product of column multiplication should be mathematically consistent to avoid the impression that the table contains incorrect values.

In summary, the SAB finds that the REF would benefit from better explanation, documentation and statistical analysis in terms of: (a) documentation of TEFs (Table 3.4), including consideration of whether the TEF for carcinogenic activity is appropriate for certain PAHs not traditionally considered as carcinogens; and (b) documentation of the methods for EEF derivation, especially with respect to better analysis of the relationship between EEF and key environmental fate characteristics of each chemical (K_{ow}, environmental persistence, molecular weight, etc.) potentially including a probabilistic analysis and, at a minimum, more complete statistical treatment of the relationship between K_{ow} and LADD.

3.3 Fishing, lake and pond assumptions

> *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 Tier 2 multipathway screening scenario replaces some of the assumptions in the Tier 1 screen and is considered more realistic than Tier 1. Specifically, site-specific information is used for the locations of potentially fishable lakes and for meteorology. In addition, the Tier 2 assessment includes: a screening configuration that assesses the fisher and farmer exposure scenarios separately; and an estimation of lake productivity and fish population dynamics. The consideration is that a fisher might catch and consume fish from more than one nearby contaminated lake because more than one lake might be needed to catch enough fish for subsistence living. The approach at this level of screening analysis also attempts to account for PB-HAP deposition into a lake from multiple facilities in the same RTR source category.

3.3.1 Human fishing behavior and sustainability of fish populations in ponds and lakes

The SAB finds the assumptions used for human fishing behavior in the refined fishing scenario to be appropriate with caveats as noted below, while the assumptions concerning sustainability of fish populations in ponds and lakes may be inappropriately conservative. Assuming all parameters (such as size of the lake needed to support fish of a given size, assumptions about fish populations, etc.) are correct, the approach used seems reasonable. The equations seem appropriate and the assumptions appear to be properly managed. However, the SAB finds that most of the assumptions/parameters are possibly too conservative to achieve the objective of effective risk screening and suggests that more realistic ingestion rates and other model parameters be considered. For example, the Tier 2 method limits the fish consumption rate from a local water body due to potential depletion of fish by a single subsistence fisherman. 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, in one study the productivity of lakes was 82 kg/hectare/year (N=22 lakes, Randall et al. 1995) which converts to 90 g/acre/day. This 90-fold difference indicates the EPA should reconsider lake productivity and how to relate it to fish consumption estimates for a specific lake. Furthermore, with some of the contaminants examined, fish will not take up 100% of the chemical. Also, the chemicals considered will have different toxicodynamic and toxicokinetic properties in the fish, making the half-life of some chemicals (PABs/dioxins) much shorter than values assumed. These issues will affect exposure estimates in the fisher population.

There is considerable heterogeneity across lakes and the SAB has concerns with the presumed universality of some of the assumptions invoked for the analysis. For example, the analysis assumes: 21% of the fish biomass are piscivores; benthic fish account for 17.5% and pelagic fish account for 3.5% of total fish biomass; humans consume 50:50% from benthic and pelagic piscivores (note some people consume pan fish); and total fish biomass is 40 g fish ww/m^2. It seems likely that rather than fixed values these parameters have a wide range of occurrence in actual lakes. Also, as explained in the appendix of the Agency's draft RTR methods document, benthic fish collection is usually higher than pelagic species (although pelagic are preferred by consumers) due to the general species abundance. The SAB recommends that the EPA document and justify these assumptions.

The SAB encourages the EPA to consider other data available to make more realistic assumptions such as using the most recent NHANES data to estimate fish consumption. Additionally, the EPA might be able to refine the assumptions on chemical runoff and erosion from the watershed by using relevant U.S. Geological Survey (USGS) data that are available for the region of interest (U.S.G.S. 2018). As another example, the EPA Risk-Screening Environmental Indicators (RSEI) Model is part of the Toxics Release Inventory (TRI) program and is primarily used as a transport and fate model to estimate concentrations, hazard level and risk of air pollutants covered by the TRI. However, RSEI also has a model that estimates transport and fate of TRI releases to water bodies including both direct releases and transfers between wastewater plants. The primary data product is toxicity-weighted concentrations downstream of TRI discharges. These data are available by stream segment. The Office of Pollution Prevention and Toxics could presumably prepare data specific to the modeler's needs. Alternatively, the RSEI Water Microdata can also be accessed online (U.S. EPA 2018i).

The SAB struggled with understanding some of the RTR modeling inputs/assumptions. This process may become more transparent if the data are presented with information about how studies were included or excluded, how data were prioritized and selected for use, how the evidence was weighted, etc. The appendices to the EPA report achieve this goal to a certain extent but are incomplete.

3.3.2 PB-HAP deposition to lakes

The SAB could not determine whether the assumptions for PB-HAP deposition to lakes are appropriate for the following reasons. Regarding PB-HAP transport and deposition, air dispersion models recommended by EPA, such as AERMOD, have been continuously improved and updated many times over the years (as recently as January 2017). Such models have been used by many users in a variety of regulatory applications and have been subject to rigorous performance evaluation by EPA and the scientific community to test and demonstrate their accuracy. The SAB recommends clarification of the extent to which TRIM.FaTE has been updated since 2002, when its technical support document was released. Assuming AERMOD is valid for the use cases of interest, the reliability of TRIM.FaTE's air dispersion component should be assessed by comparing to AERMOD for a variety of scenarios. Also, the EPA may seek to consult with EPA Office of Pesticide Programs (OPP) Environmental Fate and Effects Division (EFED) since they have developed models with different tiered assumptions about runoff into ponds.

It is unclear how accurately PB-HAP deposition is calculated by TRIM.FaTE. Additional information is needed to demonstrate the accuracy (or for a screening methodology, to evaluate how conservative the assumptions are) of such deposition estimates and their implications to the reliability of fish consumption exposure estimates. EPA should test and demonstrate for a range of representative scenarios the reliability of TRIM.FaTE air concentration and deposition estimates.

Finally, the SAB recommends conducting a sensitivity analysis of the distribution of critical parameters at higher tiers. The use of multiple health-protective assumptions/parameters is likely to overestimate the actual risks, probably by a substantial margin. Furthermore, a probabilistic analysis should provide a more accurate and transparent estimate regarding uncertainty of the risks and may be appropriate at higher tiers.

3.4 Lake data, plume rise, and meteorological data

> *Charge Question 4: Does the SAB find the methods used for evaluations of (1) lake data, (2) plume rise, and (3) time-series meteorological and time-series plume-rise data are appropriate?*

When the Tier 2 screening analysis indicates that further evaluation is warranted, the EPA applies the Tier 3 screening approach described in Section 3.3 of the Agency's draft RTR methods document. The method includes three individual refinements to the Tier 2 methods that are conducted in a step-wise fashion. The refinements include: further analysis of the affected lakes identified in the Tier 2 screen; analysis of plume rise resulting in PB-HAPs lost to the upper atmosphere; and the use of time-series meteorology from meteorological data stations and modeled effective chemical release heights.

3.4.1 Lake data

The SAB finds the method to evaluate lake data to be generally appropriate and indicates items for refinement. The SAB supports the use of up-to-date land-use data to more accurately represent exposures that occur through lake media. EPA should consider relying less on analyses that are time-intensive and that depend on analysts' subjective judgments. Web or GIS searches, as described in the Agency's draft RTR methods document, may be useful to produce input data. 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.

EPA should consider the use of data streams that can be automated so that ongoing land use changes can be incorporated. Widely available data sets include the National Land Cover Database (NLCD) and USGS Digital Elevation Model (DEM). The SAB cautions EPA against *a priori* exclusion of wetland influenced lakes, which may host fish.

3.4.2 Plume rise

The SAB believes the plume rise methodology may be inappropriate in some cases EPA should evaluate the use of plume-rise models other than those described in the Agency's draft RTR methods document screening procedure. An example is Briggs (1984) and the documentation of AERMOD (Cimorelli *et al.* 2004) which thoroughly discusses plume rise and contains other citations.

For this and other dispersion and transport modeling, the SAB recommends that EPA consider the use of meteorological reanalysis data for both surface-air and upper-air wind speeds. These data can overcome some uncertainties when weather stations are far from the modeled site.

3.4.3 Time series meteorological and plume-rise data

The SAB believes that the hour-by-hour response treatment is not yet justified. Furthermore, the corresponding time-series meteorological and time-series plume-rise data used in the hour-by-hour treatment may be inappropriate in some cases.

First, EPA should be cautious about undue oversimplification of complex atmospheric processes. Full or partial penetration of a plume through the top of the mixed layer depends on many complex factors including plume momentum, plume buoyancy, stack release height and exit conditions, depth of the mixed layer, inversion strength, and atmospheric stability. These processes may vary with time, as meteorological factors evolve over the course of a day, possibly causing plume re-entrainment or rapid fumigation. Atmospheric processes governing plume penetration are more complex than can be adequately represented by a simple comparison of inversion height with effective plume height (which includes plume rise).

Second, the Agency's draft RTR methods document indicates that hour-by-hour data from the closest meteorological station should be used. These data may not reflect specific microclimatic conditions at the site, including topography, directional valley orientations, and specific inversion conditions that can differ from those at the station. For accurate screening, these local conditions should be considered.

EPA should test and demonstrate the reliability of the proposed adjustment by comparing screening results as implemented using TRIM.FaTE to those calculated by a more physically realistic model, such as AERMOD. Indeed, the SAB suggests EPA evaluate the additional accuracy perceived to result from implementing hour-by-hour adjustments. The suggested procedure requires extensive data manipulation yet has not been validated, whereas with a moderate additional investment the screening could be done with a validated and accepted model such as AERMOD.

The SAB also has two overarching recommendations addressing issues which were not specifically called out in the charge questions.

- EPA should consider that the quantity of emissions in the National Emission Inventory (NEI) may differ from reality, either because of upset conditions, or because self-reporting does not always suffice. The location of emissions may also be different than reported. These inaccuracies may have important effects on predicted exposures and should be assessed to the extent practicable.

- The SAB recommends that EPA consider sensitivity analysis to determine the parameters and assumptions that have the greatest effect on predicted exposures, especially at the higher tiers. Identification of factors that dominate risk and uncertainty could guide future screening analyses by providing justification to obtain detailed input data for those factors. Furthermore, probabilistic analysis would provide a framework to estimate confidence bounds.

3.5 The gardener scenario

> *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?*

The Agency's draft RTR methods document includes a new exposure pathway added to the EPA methods (Section 3.4) – a gardening exposure scenario added to the multipathway screen. This scenario is intended to better characterize multipathway risk and the EPA suggested it will significantly improve the screening for locations where the presence of a subsistence farm is either unlikely (in urban areas) or difficult to confirm based on the characterization of land use surrounding a facility.

The gardener scenario is described on pages 59-62 of the Agency's draft RTR methods document. EPA is proposing to implement this scenario as part of Tiers 2 and 3 in locations where at least some individuals are likely to consume homegrown produce. The SAB was asked to comment on the assumptions used and whether the addition of the scenario would improve characterization of ingestion risk in both urban and rural environments. In general, the SAB finds that the gardener scenario is an appropriate addition to both Tier 2 and Tier 3 evaluation thereby developing a more useful model system for screening.

Regarding the first component of the charge question – the appropriateness of assumptions and approaches in the scenario – the SAB's response focuses on the media ingested by the gardener. EPA has selected ingestion routes like those experienced by subsistence farmers. These categories include direct ingestion of soil, ingestion of protected fruits and vegetables, ingestion of root vegetables, and ingestion of breastmilk (although intake rates for the latter are not presented in Tables 3-18 and 3-19). These appear to be appropriate and sufficiently distinct to provide coverage of the appropriate sources of soil ingestion and contaminants contained in soil. EPA distinguishes intake of gardeners from farmers by noting that meat products and dairy products are not likely to be sources for the gardeners (Table 3-17).

The SAB suggests including chicken eggs in the gardener scenario as many gardeners also keep egg-laying chickens. The SAB also notes that the gardening scenario appears to use many of the same assumptions about diet as the subsistence farmer, suggesting that the gardening scenario does not add much value to the tiered approach. The SAB therefore suggests that it is especially important to distinguish between the gardener and the subsistence farmer.

EPA has separated gardeners into two categories – rural and urban. The approach seems reasonable, especially given differing intake rates for urban and rural gardeners. The assumptions that a rural gardener would have enough land to develop a subsistence, or near-subsistence, garden while the urban gardener would not seem, on face value, to be valid. Following this reasoning, EPA uses an upper (90th) percentile estimate for intake rate of home-grown vegetables for the rural gardener but a central tendency home-grown vegetables intake rate for urban gardeners (See Table 3-19 for the intake rates). Both intake rates are taken from the Exposure Factors Handbook and appear to be justified as EPA's best assessment of such rates.

Regarding soil intake rates, gardener soil intake rates were matched to those of farmers, consistent with the notion that gardens in both rural and urban settings must be tended, affording gardeners with intimate soil contact and thus intake. Further, in the rural setting, the farmer-specific rates for surface runoff-related contamination would be used while this term would not be used in urban settings. The farmer-specific rates are less health-protective in the sense that it focuses only on agricultural runoff. In urban settings, runoff may occur from other sources (e.g., industrial facilities and roadways) and might well be considered important. The SAB suggests that these additional urban sources be considered and matched with those of the rural settings.

Except for the surface runoff component, the assumptions made above are health-protective but not unreasonably so even when compared to earlier assumptions (e.g., Charge Question 3). The SAB notes that including the same assumptions for multiple tiers likely results in little effective screening. Further, the assumptions may offer too much health protection and thereby reduce the screening utility of the tool. In addition, the SAB suggests alternative- and higher- soil intake rates for the adult gardener.

Regarding the second component of this charge question, inclusion of the gardener scenario is appropriate because it improves the characterization of the potential risk in both rural and urban environments for those who take part in this activity.

3.6 Environmental risk screening methodology

> *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?*

Charge Question 6 addresses the information provided in Chapter 4 of the Agency's draft RTR methods document (and supporting appendices) that describes the environmental risk screen that was developed to provide a systematic, scientifically defensible, and efficient approach that EPA can use to screen for potential adverse environmental effects associated with emissions of HAPs from facilities in RTR source categories. It is designed so that the screen can be run quickly and with minimal additional data gathering by drawing on existing data, models, and modeling results, including those developed for the human health multipathway risk screen. The overall methodology was reviewed by the SAB in 2009. The material in Chapter 4 of the Agency's draft RTR methods document focused on those aspects that have been refined/revised since the last review. The revised aspects include:

- Modeled environmental concentrations are compared to ecological benchmarks, not human health thresholds, for all pollutants included in the screen;
- An evaluation of HAPs for potential inclusion in the screen was conducted;
- The environmental risk screen was expanded to include the following additional environmental HAPs: cadmium, hydrogen fluoride, lead, arsenic, and additional POMs;
- The number of ecological endpoints and effect levels that are evaluated was expanded;
- A literature review was conducted to identify the most up-to-date ecological benchmarks; and
- Tiers were added to the environmental risk screen for PB-HAP that are parallel to the tiers in the multipathway human exposure screen.

The SAB finds that the overall methodology and specifically the revisions since 2009 are appropriate and improve the ecological assessment capabilities. It represents a comprehensive approach that builds upon, and uses, the screening tools used in the health assessment/screening (i.e., TRIM.FaTE, AERMOD). As noted below, the SAB offers several recommendations and comments towards refining the approach.

The methodology for identifying the pollutants to be included in the screening activities are clearly stated and the criteria used to prioritize the chemicals are judged to be appropriate with the following considerations to be taken into account. The SAB is concerned that selenium is not included as a chemical to screen. Selenium is an essential trace element which is toxic at elevated concentrations. Elevated exposure can lead to selenosis. Selenates and selenites are particularly toxic forms of selenium (Hamilton, 2004). Given selenium's potentially important role in ecological impacts, the SAB recommends it be considered. In addition, it is not clear that BaP is the most appropriate POM chemical to use in the ecological analysis. There may be more important POM molecules (lower molecular weights) to use in this screening and further analysis is recommended. Furthermore, the emission rates presented in Table 4.1 are for base year 2005, and they need to be updated to reflect recent emissions data. Also, on page 67 line 21 there is reference to "99.9% of national emissions" but the basis is not clear (mass, toxicity or some other basis).

The SAB finds the expansion of ecological assessment endpoints appropriate and that the benchmarks, and the use of a tier system, are justified. The Agency's draft RTR methods report and appendices document the processes and assumptions used to identify the endpoints and benchmarks. Overall, the calculation of potential risks is robust and follows current scientific methodologies. As the amount and diversity of information analyzed in identifying the endpoints and benchmarks is vast, it would be helpful to clarify when most sensitive or most exposed species are used. In addition, the SAB notes that the overall approach would be strengthened by allowing site-specific variables to be added during the assessments, as some sites may have very specific sensitive species. Using a less sensitive receptor in a screening methodology runs the risk of underestimating the impact to the environment in those regions.

Tables 4.2 (endpoints) and 4.3 (benchmarks) are critical to the screening process. Values in these tables are likely to change over time as new information becomes available so it is important that they be viewed as tables requiring continuous development and a process should be identified by the EPA to continuously review and update them. Furthermore, many of the studies listed are from the 1980s-1990s and are compilation reviews from earlier publications. Notations should be made in the table or the text as to why the benchmark value was chosen. Many of the benchmarks have multiple studies (chronic / acute) with varying methodologies and results. The SAB recommends the EPA consider grading studies based on Klimisch score, a method of assessing the reliability of toxicological studies, mainly for regulatory purposes.

The SAB finds that the general methodology of the tiered approach and the use of TRIM.FaTE and AERMOD are appropriate. The SAB notes the simplicity of the air dispersion treatment in TRIM.FaTE and encourages the advancement of incorporating AERMOD analysis within the TRIM.FaTE framework. The use of reanalysis meteorological data is recommended to improve the meteorological fields used in the analysis. As stated elsewhere in this report, the analysis would also benefit from considering the implementation of a probabilistic approach.

The SAB recommends that analysis elements performed under the environmental risk screen be incorporated in the farmer screen (e.g., utilizing the deposition to soils).

The following additional specific recommendations regarding endpoints and benchmarks are provided:

- The SAB suggests EPA consider indirect HCl effects by evaluating the concentrations of chloride from a facility relative to background chloride concentrations contributing to loss of surface water acid neutralizing capacity or soil base saturation. Critical loads of acidity have been developed (NADP 2018) for the U.S. and the acidity associated with estimated chloride deposition could be compared to these critical load values.
- Mercury targets may need to be updated or expanded to protect communities of predator animals associated with bioaccumulation of methylmercury and to reflect broader wildlife impacts[4] (e.g., song birds.)
- The water quality and soil criteria (Table 4-1) for mercury are very high. This is particularly true for water where concentrations are typically on the order of nanograms per liter (ng/L). For 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. The SAB suggests EPA consider criteria values for water and sediment/soil for contaminants that have been established for hazardous waste clean-up at sites around the U.S. for several contaminants.

3.7 Inhalation risk assessment enhancements

[4] http://www.briloon.org/uploads/Library/item/265/file/Hidden%20Risk.pdf https://www.crcpress.com/Environmental-Contaminants-in-Biota-Interpreting-Tissue-Concentrations/Beyer-Meador/p/book/9781420084054https://www.niehs.nih.gov/research/supported/assets/docs/a_c/bioscience_508.pdf

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?

In previous chronic inhalation risk assessments, the EPA assumed the land surrounding each facility was rural. The 2009 SAB review (U.S. EPA SAB 2010) indicated additional development was appropriate. Chapter 5 of the Agency's draft RTR methods document is an enhancement to the chronic inhalation risk assessment that the EPA contends accounts for the variation in urban to rural characteristics of the land surrounding each evaluated facility. The goal of the improvement is to better characterize pollutant dispersion near sources.

The urban/rural dispersion selection enhancement tool provides a way to specify atmospheric turbulence within a model domain to allow AERMOD to more accurately model pollution dispersion. The tool currently provides two options. The Agency's draft RTR methods document evaluates the differences in model results using these two methods and proposes using the census (population density)-based designation of "urban" ("HEM default procedure") as the preferred method.

The SAB agrees that incorporating the effects of turbulence as a model input is appropriate and of significant value because it avoids the overly conservative assumption of applying the "rural" assumption to all facilities. However, the SAB disagrees with the Agency's draft RTR methods document on the procedure of choice and recommends the land use procedure which uses the National Land Cover Database (NLCD). This procedure directly measures the feature that controls turbulence, unlike the HEM default procedure which relies on a secondary effect – an aggregated population density metric – that may not correlate well in highly industrialized areas with dense concentrations of buildings, pavement and other structures yet little residential land. The land use procedure provides a more accurate assessment for the selection, and the Agency's draft RTR methods document does not offer a compelling explanation of the benefits from using the HEM default procedure. The land use procedure also more directly aligns with EPA's 2005 Guidelines on Air Quality Models as stated on page 121 (last paragraph) in the Agency's draft RTR methods document; the guidelines list specific land use types to be considered, rather than population density.

Using the land use procedure is not significantly more difficult or time/resource intensive than the HEM default procedure, so any logistical advantage of the HEM default procedure is minimal. Analysis can be automated using Model Builder or Python scripting in ArcGIS. Problems described in the Agency's draft RTR methods document associated with the land use procedure misclassifying facilities with significant coverage by water bodies inside the model domain can be addressed in the GIS procedures, and the SAB recommends that this be included in the procedure to avoid misclassifying heavily developed areas near large water bodies as "rural."

Because the inhalation risk assessment is a location-based estimate using modeled ambient concentrations and is not population-weighted, the use of population density via the HEM default procedure is less appropriate than using land use. In addition, the land use procedure finds fewer urban areas than the HEM default procedure, indicating the latter misclassifies turbulence in some cases.

The SAB also notes that the quality of the NLCD data makes it possible to express the "urban nature" of the model domain as a continuous variable, rather than a binary "yes/no" value. Such a calculation adds little to the time and difficulty of the GIS procedures used to calculate the variable. It provides a measure of the intensity of "urban" character for each area considered and could also be used to characterize the geographic variation of turbulence within a given model domain. There are different ways to use this type of metric in modeling; it is not certain whether EPA modeling tools can use that variation, but it might be useful in future versions of the modeling and represents a "best practices" approach for gathering input data, particularly if it is only a little more difficult or expensive to do so. Using this approach with successive versions of the NLCD, which is updated every four years, allows for tracking land cover change over time.

If EPA adopts this more nuanced use of the NLCD, the SAB suggests the EPA consider including NLCD class 22 (low intensity developed) in identifying "urban" in this context. This class is defined as 20-44% impervious surfaces and it correlates very well with residential land use when compared to other high-resolution datasets. Class 22 is used in screening methods in California and has been shown to be of value in characterizing or measuring fine scale heterogeneity in other contexts (Chabaeva and Civco 2004; Smith et al. 2010).

Another alternative is the use of a regular NLCD derivative product – the percent impervious surface data layer which is produced for each NLCD generation, as is a measure of the net change in imperviousness between NLCD generations. Use of these metrics are generally as cost effective as using population density and have the advantage of being updated more often than the census. The SAB looks forward to reviewing and commenting on the approach eventually adopted.

Regardless of the urban/rural dispersion selection procedure that is used, the automatically-generated designation should be manually evaluated with the final choice of urban/rural dispersion a matter of professional judgment based on 'facts on the ground.' In cases where a material difference in estimated potential risk exists between urban and rural dispersion and professional judgement is used to overrule the selection tool's designation, EPA should document and justify this decision.

3.8 The census block receptor check tool

> *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?*

Section 5.2 of the Agency's draft methods document describes an enhancement made to the chronic inhalation risk assessment – the addition of the Census Block Receptor Check Tool. The rationale for the new tool is that the block centroid does not always represent residential locations. The HEM-3 model calculates ambient air concentrations at census block centroid locations as surrogates for population exposure. If the centroid is located outside of the block polygon, then the U.S. Census Bureau provides the longitude and latitude of an internal point near the geometric centroid that falls inside the block polygon. The points are not weighted or reflective of the population distribution. Census blocks vary in size depending on population density. In urban areas, a census block may be equivalent to a city block bounded on all sides by a street. In sparsely populated areas, a census block is often irregularly shaped with streams, property lines, and rural roads as boundaries. In the 2009 review conducted by the

SAB (U.S. EPA SAB 2010) it was noted that census block centroids might not always be an appropriate surrogate for residential locations. The Census Block Receptor Check Tool was developed to address this concern. This new tool identifies two examples when internal centroid points may not be a good surrogate for where populations reside and provides options to address this.

The first scenario is for block centroids located within 300 meters of emission points, which may be within the facility grounds and not where there are residents. The tool user would be able to view these receptors and delete them if they are on the facility property. The second scenario focuses on large and irregularly shaped census blocks, where the centroid may be farther away from population centers. If blocks with an area greater than 2.6 km^2 are identified within 1 km of a facility, aerial images of the blocks can be examined using the tool to determine if the centroid receptor needs to be relocated and other receptors added to represent multiple residential locations.

The SAB finds the Census Block Receptor Check Tool to be an appropriate framework, but the precise methodology underlying the tool may be unreliable in some cases. The SAB offers recommendations for improving the method, but also encourages the Agency to consider an alternative approach.

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. For example, the statement "If residential locations cannot be represented by a single receptor (that is, the residences are spread over the block), additional receptors are added for residences nearer to the facility than the centroid" (page 140, lines 15-17) is vague and the method appears to be *ad hoc*. The SAB is concerned that the process would not be reproducible if another risk assessor were to subsequently model that facility. The choice of a 300-meter buffer from an emission source is also somewhat arbitrary. Furthermore, the impact of these changes is not obvious. The Agency's draft RTR methods report should include more detailed examples of how risk estimates change based on these enhancements compared to the default block centroid method.

Overall, the SAB believes that methods predominantly relying on census block centroid locations – including cases where the enhancement tool is applied – can in some cases be reliable, but additional effort is needed to verify that receptors are representative of residential areas near the facilities. One approach would be to review satellite imagery within 1 km of all facilities, not just those in identified large census blocks, and manually add receptors as needed to appropriately represent population centers. However, any manual placement would be subjective and likely not reproducible between risk assessors. The SAB recommends the Agency evaluate an alternative approach that uses the same 2011 National Land Cover data used for the Urban/Rural Dispersion Selection Enhancement tool to automate the process of identifying population centers. The NLCD data is available at a high spatial resolution (30 m) and receptors could be placed in areas of developed land use classes 22-24. Aerial photos (e.g. Google Earth™) can then be used to check that the land use-based placement of receptors is appropriate. If professional judgement is used to select the location then the RTR screening analysis documentation should include sufficient information such that another expert could follow the reasoning and reproduce the selection.

If the EPA prefers to continue using census block centroids as nearby exposure receptors, then the SAB recommends additional enhancements to make the tool less *ad hoc*. For example, facilities are better represented as polygons than points. Satellite imagery can be used to estimate the facility boundary and then GIS procedures could be used to exclude centroids located within the boundary. In such cases, satellite imagery could then be used to add alternative receptors to replace the deleted centroid and ensure nearby residences are represented. It is noted that this procedure would not be needed if receptors were placed at actual population locations using land use data as recommended.

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5. APPENDIX A: CHARGE TO THE SAB

May 26, 2017

MEMORANDUM

SUBJECT: Request for SAB Peer Review of the document: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis"

FROM: Erika N. Sasser, Director /s/
Health and Environmental Impacts Division
Office of Air Quality Planning and Standards (C504-02)

TO: Christopher Zarba, Director
EPA Science Advisory Board Staff Office (1400F)

EPA's Office of Air Quality Planning and Standards is requesting a peer review by the Science Advisory Board (SAB) on the document: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis." This report describes specific screening methodologies that have evolved since the SAB last reviewed the RTR risk assessment methods in 2009. The screening methodologies are used to quickly identify those facilities in particular RTR source categories that have little potential for human health multipathway or environmental risk, while also identifying those facilities where a refined multipathway or environmental risk assessment may be needed. This report also describes the potential addition of a new multipathway exposure scenario that can estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables, as well as several improvements to EPA's chronic inhalation risk assessment methodology. The application of the updated risk assessment screens and methodologies is highlighted in this report through the presentation of example facilities emitting hazardous air pollutants.

The case study analysis and accompanying documentation were prepared by staff in the EPA's Office of Air Quality Planning and Standards. The document is being made publicly available on the Agency's website at the following address:
https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.

Attached is the charge to the Science Advisory Board. It includes background information on the screening methodologies and identifies the questions and issues we would like the Science Advisory Board to address in their peer review of the methods.

Attachment:
Peer Review Charge

Attachment

Charge to the Science Advisory Board for their review of the "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis"

Office of Air Quality Planning and Standards
Office of Air and Radiation

Background:

The Clean Air Act (CAA) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the CAA requires the EPA to develop technology-based standards for categories of industrial sources. We have largely completed the required Maximum Achievable Control Technology (MACT) standards with about 112 MACT standards being issued to date for stationary major sources of HAP. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." EPA is also required to complete a one-time assessment of the human health and environmental risks that remain after sources come into compliance with MACT. If additional risk reductions are deemed necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects that are judged to be "significant and widespread", EPA must develop standards to address these remaining risks. For each source category for which EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR. In this way, the results of the risk review can be potentially informative to the technology review process, and vice versa.

Because RTR assessments are used for regulatory purposes, and because components of our screening analyses have evolved over time, EPA periodically seeks the Science Advisory Board's (SAB) review (see below). For the current review, we seek the SAB's input on the specific enhancements made to our risk assessment methodologies, particularly with respect to multipathway and environmental screening methodologies, since the last SAB review was completed in 2009. Facilities that do not screen out may be the subject of refined multipathway risk assessments, which 1) are conducted for a single facility at a time; 2) are very costly; 3) and can take several months to complete. Thus, we consider these screens to be an important step in the RTR risk assessment process that helps the agency to maximize the use of its resources and, when appropriate, to facilitate its communication with stakeholders.

Previous Relevant Peer Reviews

Previous peer reviews have covered various elements associated with the RTR process. A brief summary of each peer review is provided:

1) The *Residual Risk Report to Congress*, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf).

2) A peer review of multipathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$Fi le/ecadv05.pdf.

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in 2006. The final SAB advisory is available at https://yosemite.epa.gov/sab%5Csabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf.

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!Ope nDocument&TableRow=2.3#2.

5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA; and the Agency for Toxic Substances and Disease Registry, or ATSDR).

We are not asking the SAB panel to duplicate or comment on previously reviewed methodologies, but rather to evaluate whether the specific enhancements to previously reviewed methodologies as described below are appropriate and scientifically credible.

Goals of This Review

We are seeking a scientific peer review of the updated screening methodologies. We are also seeking a scientific peer review of several specific enhancements to our chronic inhalation risk assessment that serve to reduce some of the uncertainties identified by EPA in the last SAB review. These updates and enhancements are outlined in the report: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (the report).

The most important revisions and enhancements to our methodologies since the last SAB review include the following:

1) A tiered multipathway screening methodology that determines whether the potential for multipathway risk from persistent and bioaccumulative HAP (PB-HAP)[5]1 emitted from RTR source categories is low or whether more analysis is needed.

2) A tiered environmental screening methodology that determines whether the potential exists for adverse environmental effects from PB-HAP and the acid gases hydrogen chloride (HCl) and hydrogen fluoride (HF) emitted from RTR source categories.

3) The potential use of a new multipathway exposure scenario that can be used to estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables.

4) Enhancements to our previously reviewed inhalation risk assessment that allow us to more accurately model air concentrations where populations actually reside and to better characterize the dispersion of the air in the vicinity of sources.

Charge questions for the Panel's consideration:

There are eight charge questions for this peer review, each of which has been placed in a box below. These eight questions concern three topic areas that cover the most important revisions and enhancements to our methodology since the last SAB review.

Multipathway Human Health Risk Screening Methodology (Chapters 2 and 3):

In RTR assessments, EPA considers ingestion risks using a multipathway approach, in which we model the dispersion, transport, and fate of HAPs emitted from facilities in specific source categories in the environment and estimate human health risks resulting from the ingestion of HAPs from food products, such as vegetables, fruit, meat, and fish.

Since the 2009 SAB review of RTR methods, we refined our original one-tier multipathway screen to include a three-tiered multipathway screening approach that progressively replaces health-protective default assumptions with location-specific data. Since full-scale facility-specific multipathway assessments are time consuming and expensive, the tiered screening approach "screens out" low-risk facilities for which no additional analysis is needed, so that only facilities with potentially higher risk remain in the pool for further analysis.

Chapter 2 of the report provides an overview of the tiered multipathway screening methodology, including a brief description of each multipathway screening tier. The technical detail on each tier of the multipathway screen is laid out in Chapter 3 of the report.

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?

Tier 1

The multipathway screen previously reviewed by SAB 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). Section 3.1.2 of the Report describes the new risk equivalency factor (REF) approach that 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).

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?

Tier 2

Section 3.2 of the report describes the Tier 2 multipathway screening scenario, in which some of the health-protective assumptions in the Tier 1 screen are replaced with more site- specific information. Specifically, in the Tier 2 assessment, site-specific information is used for the locations of potentially fishable lakes and meteorology. In addition, the Tier 2 assessment includes:

- A screening configuration that assesses the fisher and farmer exposure scenarios separately (see Sections 3.2.1.2 and 3.2.1.3).
- An estimation of lake productivity (see Section 3.2.2.2).
- The consideration that a fisher might catch and consume fish from more than one nearby contaminated lake, because more than one lake might be needed to catch enough fish for subsistence living (see Section 3.2.2.3).
- An approach that accounts for PB-HAP deposition into a lake from multiple facilities in the same RTR source category (see Section 3.2.2.3).

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?

Tier 3

The Tier 3 screening approach described in Section 3.3 of the report consists of three individual refinements to Tier 2 that are conducted in a step-wise fashion. These refinements include:

- Further analysis of the affected lakes identified in the Tier 2 screen (Section 3.3.1).
- Analysis of plume rise resulting in PB-HAPs lost to the upper atmosphere (Section 3.3.2).
- The use of time-series meteorology and effective release heights (Section 3.3.3).

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.

Charge Question 4: Does the SAB find the methods used for evaluations of (1) lake data, (2) plume rise, and (3) time-series meteorological and time-series plume-rise data are appropriate?

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?

Environmental Risk Screening Methodology (Chapter 4):

Chapter 4 of the report describes the environmental risk screen that was developed to provide a systematic, scientifically defensible, and efficient approach that EPA can use to screen for potential adverse environmental effects associated with emissions of HAPs from facilities in RTR source categories. The screen can be run quickly and with minimal additional data gathering by drawing on existing data, models, and modeling results, including those developed for the human health multipathway risk screen.

The revised environmental risk screen presented in the report builds on and enhances the methods the SAB reviewed in 2009 as follows:

- Modeled environmental concentrations are compared to ecological benchmarks, not human health thresholds, for all pollutants included in the screen.
- A systematic evaluation of HAPs for potential inclusion in the screen was conducted.
- The environmental risk screen was expanded to include the following additional environmental HAPs: cadmium, hydrogen fluoride, lead, arsenic, and additional POMs.
- The number of ecological endpoints and effect levels that we evaluate was expanded.
- A comprehensive literature review was conducted to identify the most up-to-date ecological benchmarks.
- Tiers were added to the environmental risk screen for PB-HAP that are parallel to the tiers in the multipathway screen.

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?

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?

Census Block Receptor Check Tool

In its 2009 review, the SAB noted that census block centroids might not always be an appropriate surrogate for residential locations. For example, when the census block centroid is located on industrial property ("on-site"), or when a census block is large and the centroid is far from where populations actually reside, using the centroid may not be appropriate. Since 2009, we developed the census block receptor enhancement (Section 5.2) that allows us to model air concentrations more accurately where populations actually reside. Specifically, the new enhancement automatically identifies census block centroids that might be located on facility, and census blocks that are very large. When onsite or large blocks are identified, we add new receptors, delete census block centroids, or move census block centroids to represent residential locations more accurately.

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?