EPA-SAB-18-xxx

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

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

Dear Administrator Pruitt:

The Science Advisory Board (SAB) was asked by EPA's Office of Air Quality Planning and Standards (OAQPS) to review the EPA draft document entitled, "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (Draft Report, May 2017. https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html). The draft RTR document describes the Agency's methods for conducting the Clean Air Act mandated assessment of "residual risk" i.e., the risks remaining after application of maximum achievable control technology (MACT), pursuant to the National Emission Standards for Hazardous Air Pollutants (NESHAP) under Title I of the Clean Air Act.

The SAB Risk and Technology Review (RTR) Methods Review Panel deliberated on the charge questions specific to the Agency's draft RTR methods document during a July 29-30, 2017 face-to-face meeting and discussed its 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: 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. The enclosed report provides the SAB's consensus advice and recommendations. This letter briefly conveys the major findings.

The SAB commends the Agency on the technical quality of the draft RTR 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 improve the assessment capabilities. The SAB notes that the Agency's approach has the potential to achieve the Agency'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 could not assess the overall operational effectiveness such as how many facilities are screened out by the screening methods due to missing or inadequate case studies. The SAB recommends the Agency compile RTR analyses applied in regulatory activities for inclusion in future RTR documents for review. Further, the SAB recommends more evaluation of specific facilities against data measured in the field in future applications of the RTR methods. These "ground truthing" studies should be included in the next RTR methods document and provided to future reviewers for consideration.

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. The SAB finds this read-across extrapolation of environmental fate could benefit substantially from an alternative approach and has identified two options for the Agency to consider for improving the exposure equivalency factor (EEF) estimate.

The SAB makes several additional observations and recommendations. These include the conclusion that including the gardener scenario is appropriate, though additional evaluation of how many people this applies to should be conducted to determine the efficacy of the addition. Incorporation of turbulence in dispersion modeling is appropriate however the SAB suggests using a different approach. Overall, the SAB found that the method's reliance on census block centroid locations was not sufficient to ensure that receptors are representative of residential areas near the facilities, and there was concern that any manual placement would be subjective and not reproducible between risk assessors. The SAB suggests alternative methods using land use data.

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 agency's response.

Sincerely,

Enclosure

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to the problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. Reports of the EPA Science Advisory Board are posted on the EPA website at http://www.epa.gov/sab.

U.S. Environmental Protection Agency
Science Advisory Board
Risk and Technology Review (RTR) Method Review Panel

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Acronyms and Abbreviations

AERMOD	Atmospheric 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
CalEPA	California Environmental Protection Agency
EEF	exposure equivalency factor
ERA	Ecological Risk Assessment
ERPG	Emergency Response Planning Guidelines
HAP	Hazardous Air Pollutant
IRIS	Integrated Risk Assessment System
LADD	lifetime average daily dose
LOAEL	Low Observed Adverse Effect Level
MACT	Maximum Achievable Control Technology
MTBE	Methyl Tertiary Butyl Ether
MIR	Maximum Individual Risks
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
REL	Reference Exposure Levels
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
TRV	Toxicity Reference Values
TWE	Toxicity Weighted Emissions
UCL	Upper Confidence Limit
USDA	US Department of Agriculture
USGS	US Geological Survey

1. EXECUTIVE SUMMARY

This report was prepared by the 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*" (Draft Report, May 2017. https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html). This document (hereafter referred to as the "Agency's draft RTR methods document" or "the draft RTR methods document") describes the Agency's methods for assessing "residual risk" i.e., the risks remaining after application of maximum achievable control technology (MACT) pursuant to the National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations.

The 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 for the three-tiered multipathway chronic human exposure approach and the approach for environmental risk screening.

The SAB reviewed the draft RTR methods document as requested by considering eight charge questions posed by the Agency. The SAB provides comments on the RTR methods and does not address the regulatory implications of the method 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 Agency.

The SAB Risk and Technology Review 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 [insert date]. 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 Agency 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 improve the assessment capabilities.

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 Agency RTR risk assessment screening, and not just for the audience of peer reviewers. The SAB also finds the case studies to be missing or inadequate for a thorough or detailed assessment of the application of the methods described. The SAB, therefore, could not assess the operational effectiveness, in aggregate, such as how many facilities are screened out, or passed to more detailed analysis, by the screening methods. The SAB recommends the Agency compile RTR analyses applied in regulatory activities for inclusion in future RTR documents for review. Further, the SAB recommends more evaluation of specific facility analyses against data measured in the field for specific cases of industries and facilities modeled in future application of the RTR methods. These "ground truth" studies should be included in the next RTR methods document and provided to future SAB reviewers for consideration.

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 general quality of the Agency's draft RTR methods document or the screening and assessment efforts to date.

The SAB agrees that the use of the proposed three-tier multi-pathway risk screening approach, starting with health protective parameters and moving to more site-specific and realistic parameters in later tiers, seems reasonable and logical. The SAB finds that the expansion of the endpoints for the environmental risk screen are reasonable and that the benchmarks, and the use of a tiered system overall, are justified. The SAB notes that the proposed approach has the potential to achieve the Agency'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.

Overarching data quality considerations are important in the assessment. 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. The SAB recommends that analyses be conducted to confirm that the tiers behave as desired.

Toward this end, the Agency should apply the three-tiered approach on actual sites, either new sites or previously evaluated sites, to determine how well the approach performs. Using actual sites would also help "ground truth" the evaluations. It would also be useful to know the contribution of each tier in improving the screen. Field measurements with available monitoring data on relevant persistent bioaccumulative hazardous air pollutants (PB-HAPs) in atmospheric deposition, soil, water, and fish could also be used in a selective manner to validate key points in the Tier 3 evaluation. 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 do a better screening analysis for particular source categories in the future.

The SAB recommends conducting a probabilistic analysis of the distribution of critical parameters. The use of multiple health-protective assumptions and parameters is likely to

overestimate the actual risks, probably by a substantial margin. Many parameters and assumptions appear to be based on in-house policy decisions. At times, it is unclear what criteria are decisive in selecting the model inputs and how those criteria are influencing the screening results. The probabilistic analysis should allow a more accurate and transparent estimate of the risks including estimating confidence bounds resulting in more efficient resource expenditures and more transparent decisions by the Agency.

Regarding the *risk equivalency factor* (REF) approach the SAB is in agreement with the toxicity equivalency factor (TEF) approach as it is well accepted for dioxins and carcinogenic polycyclic aromatic hydrocarbons (PAHs).

EPA's empirical correlation between the n-octanol water partitioning 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 Agency. However, K_{ow} is an imperfect predictor of LADD. The read-across approach for environmental fate is less well tested and accepted for the Agency's RTR screening application and thus deserves further consideration. The SAB finds this read-across extrapolation of environmental fate could benefit substantially from an alternative approach and has identified two options for the Agency to consider for improving the exposure equivalency factor (EEF) estimate.

In summary, the SAB finds that the REF method would greatly benefit from better explanation, documentation and statistical analysis in terms of: a) documentation of TEFs, 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, and molecular weight) potentially including a probabilistic analysis, and at a minimum, more complete statistical treatment of the relationship between K_{ow} and LADD.

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 Agency for data and modeling methods.

EPA could consider the use of plume-rise models other than those described in the Agency's draft RTR methods document. EPA could test and demonstrate the reliability of the adjustment for plume rise. The SAB suggest's EPA conduct an evaluation of urban vs. rural terrain in the inhalation risk assessments by comparing screening results, as implemented using TRIM.FaTE, to those calculated by a more physically realistic model, such as the regularly updated AERMOD. The procedure described in the Agency's draft RTR methods document 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. 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.

In general, there was agreement among the SAB members that the Gardener Scenario is an appropriate addition to both Tier 2 and Tier 3 screening evaluation. It is important to distinguish between the Gardner and the Subsistence Farmer. Inclusion of the Gardener scenario affords improvement in characterization of the risk in both Rural and Urban environments for those who take part in this activity, however the SAB urges the Agency to gather data characterizing the population engaged in this activity, and exposure route, and evaluate the efficacy of the inclusion.

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 judged to be appropriate. The SAB is concerned that Selenium is not included as a chemical to screen and recommends this chemical be added in future RTR screening analyses.

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

The SAB finds that not enough information was provided about the census block receptor check tool, especially regarding criteria that would be 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 that facility. Overall, the SAB found that the tool's reliance on census block centroid locations was not sufficient to ensure that receptors are representative of residential areas near the facilities.

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. By the Agency's accounting, for the five most recent RTR analyses conducted, 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 Agency resources and focus attention on the subset of facilities that are not deemed low-risk based on the screening analysis. In a few cases, there was insufficient information provided for the SAB to evaluate the Agency's methods. In many cases the SAB supports the methodological details used by the Agency, in other cases the SAB recommends considering refinements or alternative approaches.

2. INTRODUCTION

EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the Science Advisory Board (SAB) review their draft document, "*Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (U.S. EPA May 2017). This document (hereinafter referred to as the "Agency's draft RTR methods document") describes the Agency's proposed 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 based on Maximum Achievable Control Technology (MACT) for categories of industrial sources. EPA must review each MACT standard at least every eight years and revise them as necessary. 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 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 process 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 Agency, in order to streamline and standardize the residual risk review for the large number of source categories at issue, 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 under review by the SAB describes the Agency's draft methodologies for conducting the risk portion of the Risk and Technology Review assessments as required by the CAA. These assessments evaluate the effects of industrial emissions of HAPs on public health and the environment. The screening methodologies 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 multipathway or environmental risk assessment may be needed. The Agency's draft RTR methods document 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 describing several improvements to EPA's chronic inhalation risk assessment methodology.

Previous internal Agency 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*, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 (U.S. EPA 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 generally been improved over the techniques described in that document.
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 (http://www.epa.gov/ttn/atw/coke/coke_rra.pdf), Perchloroethylene Dry Cleaning (http://www.epa.gov/ttn/atw/dryperc/11-14-05riskassessment.pdf), and Halogenated Solvent Cleaners (downloadable from: http://www.epa.gov/ttn/atw/degrea/halopg.html). 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 that are 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, as well as background contributions of air toxics. Because of significant uncertainties, the SAB did not believe that it was appropriate for regulatory purposes. The assessment at that time did not carry a census block-level resolution, but rather was performed at the census tract level. For this reason, on EPA's NATA website (http://www.epa.gov/ttn/atw/natamain/), the estimated risks are characterized as "starting points" for developing refined assessments.
4) 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. (http://www.epa.gov/scram001/dispersion_prefrec.htm#aermod)
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). 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 area is a source of significant, usually unquantifiable uncertainty. (IRIS - http://cfpub.epa.gov/ncea/iris/index.cfm, ATSDR - http://www.atsdr.cdc.gov/mrls/, CalEPA - http://www.oehha.org/air/toxic_contaminants/index.html)
6) An earlier peer review of multi-pathway risk assessment methodologies was conducted by the EPA's 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 SAB in 2006. The final SAB

letter to Administrator Johnson included comments of the review.(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.

Of primary interest to this review of the Agency's RTR method document are several updates and enhancements from the previous versions 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 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.
- Enhancements to the previously reviewed inhalation risk assessment that allows more accurate modeling of air concentrations where populations actually reside and to better characterize the air dispersion in the vicinity of sources.

The SAB was asked to review the current draft RTR method document by considering eight charge questions posed by the Agency. 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 call on December 5, 2017 to discuss its draft advisory report. The Chartered SAB conducted a quality review of this report on [insert date TBD]. The responses that are contained in this report represent the views of the SAB. 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?

In RTR assessments, EPA considers ingestion risks using a multipathway, tiered, screening approach. The approach applies models that simulate the dispersion, 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 resulting, in this analysis, primarily from the ingestion of HAPs from food products, such as vegetables, fruit, meat, and fish.

Since the 2009 SAB review of RTR methods the Agency has developed a three-tiered multipathway screening approach that progressively replaces health-protective default assumptions with location and facility data. Full-scale facility-specific multipathway assessments are time consuming and expensive. The tiered screening approach seeks to "screen out" low-risk facilities for which additional analysis is not cost effective. The goal is that only facilities associated with higher risks remain in the pool for further analysis.

The SAB agrees that the use of the proposed three-tier multi-pathway risk screening approach, starting with health protective parameters and moving to more site-specific and realistic parameters in later tiers, is reasonable and logical. Its general structure and intent 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 implications) and (b) low-risk facilities are not unnecessarily retained for more detailed analysis (with adverse EPA resource implications). The SAB finds that the proposed approach has the potential to achieve the Agency'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, in this case, with respect to persistent and bioaccumulative hazardous air pollutants (PB-HAPs). However, with the information presented in the draft RTR methods document, it is difficult to determine the effectiveness of the approach to screen out low-risk facilities and identify those facilities where additional analyses, and investment of resources, are warranted.

The best way to know if the three-tiered approach works as desired is for the Agency to apply the three-tiered approach on actual sites, either new sites or previously evaluated sites, and determine how well the approach performs. Using actual sites helps "ground truth" the evaluations. It would also be useful to know the contribution of each tier in screening facilities. Field measurements with available monitoring data on relevant PB-

HAPs in atmospheric deposition, soil, water, and fish could also be used in a selective manner to validate key points in the Tier 3 evaluation. In addition, analysis of the results by source category may indicate that some types of industrial facilities screen out (i.e., eliminated) earlier than others and it may point out risk drivers, sensitive parameters and key features that could be refined to do a better screening analysis for particular source categories in the future.

Key Recommendations:

EPA's tiered approach appears to be geared towards potentially protecting the most highly exposed subpopulations, combined subsistence fishers and farmers, and their children who also ingest soil. EPA indicated that the first tier is "so health protective that the potential risk for individual facilities was greatly overestimated, indicating the approach was not effectively screening out low-risk" facilities (p. 7 Agency's draft RTR methods document). SAB concurs that the first Tier is quite conservative and that individual assumptions should be evaluated within the context of all the assumptions combined together. Some of these assumptions need to be clarified and/or made more transparent as outlined below.

- Page 15 of the Agency's draft RTR methods document highlights some of the more health-protective assumptions in the Tier 1 screening scenario. EPA should list the key assumptions used in the watershed characteristics that enhance chemical loading to the lake and farm via erosion and runoff because this does not change in any of the tiers. For example, assumptions are made about the lake and whether the chemical is loaded into the lake without the water that might be moving the chemical into the lake. 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 based on more realistic scenarios.
- 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 relevant range of representative scenarios.
- Although there is refinement in the air modeling at Tiers 2 and 3, there is no comparable refinement of available 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.
- There is an apparent imbalance between refining lake and farm location information for Tiers 2 and 3 with the addition of specific lake locations relative to source but with no specific farm locations added.
- If Tier 1 is not effectively screening out low risk facilities, EPA might want to reconsider combining exposures for farming and fishing on top of other unrealistically conservative assumptions regarding weather conditions, deposition and runoff. It seems highly unlikely that the same person consumes <u>all</u> food

categories from media located close to the facility and these media receive unrealistically high-end chemical loading rates day after day.

- There appears to be very complicated reasoning for sustainable fishing used for Tier 2 that requires multiple assumptions. For the purposes of Tier 2, it seems that simpler worst-case (perhaps even unlikely) assumptions could be made that simplify the approach yet acknowledge the assumptions. Perhaps, EPA found it necessary to introduce such details at Tier 2 to be able to screen out low risk facilities. The SAB recommends that the EPA consider other data available to make more realistic assumptions, such as the most recent National Health and Nutrition Examination Survey (NHANES) results, to estimate fish consumption and/or to consider focusing on representative land use for subsistence farming based on U.S. Department of Agriculture (USDA) databases on agricultural uses.
- In Tiers 2 and 3, accounting for deposition from multiple facilities in a specific facility assessment appears to be considered (e.g., page. 44 line 15). The SAB understands that the Agency is prohibited by law from considering emission sources from another source category but it is unclear what happens if another source category facility is nearby. It would be helpful to understand how frequently this occurs. As currently constituted, the tiered approach was established without consideration of multiple source categories beyond the facilities in the specific industry under RTR analysis. It is unclear what the impact is on the final risk conclusion given that there may be significant amounts of the pollutants present in the environment from other industries' facilities.

Many of the pathways are related to those used by EPA Office of Pesticide Program (OPP), which are based on USDA Cropland Data Layer and more recent (2005-2010) NHANES dietary consumption data. These could be used to inform EPA's RTR screening approaches (e.g., 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).

There is concern about the specific values selected for the parameters, both individually and in combination. The use of multiple high-end health protective parameters can result in an excessive overestimate of risk. While each health-protective assumption on its own may seem reasonable, combining or overlaying multiple health protective assumptions can introduce a very high degree of conservatism into the result, perhaps more than is intended. An unintentionally high and unnecessary degree of conservatism is likely to render 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 getting screened out.

The SAB recommends that the EPA consider the use of probabilistic analyses of the various parameters and their combinations. This could allow the Agency to more accurately estimate overall risks at the various tiers. The SAB recommends that analyses

be conducted to verify that the tiers behave as desired. Care should be taken that none of the assumptions, by their nature, unduly drive risk-screening results. Sensitivity analyses might be helpful in evaluating the effect of assumptions, both individually and in combination. As one example, the Agency could conduct a sensitivity analysis on the impact of runoff assumptions in driving 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 Agency conducts these evaluations, it should have the flexibility to adjust its methods and the parameters as needed to ensure health-protective RTR screening occurs in future RTR screening analyses.

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 SAB recognizes the fundamental importance of accurate input data as a bedrock foundation on which all RTR risk analyses build. The Agency should continue to make meaningful efforts to ensure the validity of the data used. The possibility of errors should be considered in doing the analysis and in interpreting the results.

The focus only on cancer risk for dioxins and benzo[a]pyrene may underestimate early life (e.g., breastfeeding) risks given that 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, which is a pre-judgement that should be further explored, especially for early life exposures. We note that benzo[a]pyrene has a very recent RfD on IRIS that is based upon an early life developmental effect (https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=136). Furthermore, a number of polycyclic aromatic hydrocarbons (PAHs) with TEFs are not generally considered carcinogens and so the TEF approach for pyrene, phenanthrene, fluorene, fluoranthene, acenaphthalene and several others should be reconsidered.

Some additional items for consideration:

- The draft RTR methods document should be modified to be more explicit about decision-making on transitioning from Tier 1 to Tier 2, and from Tier 2 to Tier 3, particularly with regards to evaluating the 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.
- On page 16, the draft RTR methods document indicates that "dermal absorption of originally airborne chemicals similarly has been shown to be a relatively minor exposure pathway compared with other pathways" and cites one report from 2000 and another from 2006 to support the statement. The Agency should investigate if

the evidence still supports that conclusion and applies to all classes of chemicals. More recently, there have been several studies (Weschler and Nazaroff, 2012, 2014; Morrison et al., 2016) that have suggested that dermal absorption of certain classes of chemicals in indoor air can contribute significantly to a person's overall dose.

- 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 particular chemical emitted nearby from other industrial source categories may contribute to cumulative effects and interactions due to 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 fate and transport among polycyclic organic matter (POM) or dioxin congeners in the Tier 1 screening approach. For example, all POM congeners were assumed to move, partition, and degrade in the environment identical to BaP does, and all dioxins were assumed to exhibit the same fate and transport as 2,3,7,8-TCDD. Since 2009 when the RTR Methodology was last reviewed by the SAB the Agency has progressed significantly in its approach. Section 3.1.2 of the Agency's draft RTR methods document describes a 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 (i.e., BaP for POM and 2,3,7,8-TCDD for dioxin).

The Risk Equivalency Factor (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 that are not well characterized in terms of 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 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.

The REF Methodology consists of two read across approaches[1], one to handle toxicology data gaps, and the second to handle information gaps regarding environmental fate and transport. The SAB agrees with the toxicity equivalency factor (TEF) approach as it is well accepted for dioxins and carcinogenic PAHs. We have not checked all the values for accuracy but note that some of the PAHs given TEF factors by EPA are not typically considered to be carcinogenic (e.g., fluorene, fluoranthene, acenaphthylene, B(e)P, perylene). 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 adequate 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 exposure equivalency factor (EEF) is based upon a fundamental chemical property, the octanol to water partition coefficient (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 various types of phase transitions and partitioning. Thus, it is optimistic to expect K_{ow} by itself to have high concordance with exposure dose.

EPA's empirical correlation between K_{ow} and lifetime average daily dose (LADD) for chemicals with sufficient data (Figure 3.2) is a logical step in creating the read - across approach. However, as suggested above, Kow is an imperfect predictor of LADD. Figure 3.2 shows the relationship between K_{ow} and LADD for 14 POM analytes for which there is more complete data. There is considerable variability around the regression line in Fig 3.2 with this variability currently unexplored but may have to do with uncertainty and variability in the underlying parameters used to calculate LADD including Kow, intermedia partition coefficients, molecular weight, half-life, potential for biodegradation, etc. The variability around the regression line is two orders of magnitude in the most variable region suggesting that the calculated EEF may yield a substantial underestimate of LADD for some undefined members of data poor chemical classes.

The SAB finds this read across extrapolation of environmental fate could benefit substantially from an alternative 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 yield an upper bound on the regression slope and then apply this to derive EEFs for data poor chemicals;
- Conduct further evaluation of the underlying fate and transport parameters to develop distributions for each influential parameter and then perform a probabilistic

[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)

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 that the current documentation of key parameter inputs to this 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 of 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 product of the EEF and TEF columns do not always equal the corresponding REF. While close, it appears that rounding prior to the multiplication may cause the difference. Whatever the reason, the product of column multiplication should be mathematically correct to avoid the impression that the table contains incorrect calculations.

The Agency's draft RTR methods document does not indicate which parameters have the greatest influence on LADD and how influential the K_{ow} is relative to everything else. It may be that a combination of fate parameters would provide a better modeling basis to address this part of the REF.

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 Kow and LADD (Figure 3.2).

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?

Going beyond the Tier 1 screen, the Tier 2 multipathway screening scenario replaces some of the assumptions in the Tier 1 screen. The replacements are considered more health-protective than Tier 1. Replacements include more site-specific information. Specifically,

in the Tier 2 assessment, 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 (see Sections 3.2.1.2 and 3.2.1.3); and an estimation of lake productivity (see Section 3.2.2.2). 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 (see Section 3.2.2.3). 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 (see Section 3.2.2.3).

The SAB is generally supportive of the assumptions used for human fishing behavior in the refined fishing scenario. Assuming all of the 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 quite health-protective, possibly too conservative. Since the overall scenario indicated by the EPA is highly unlikely, the SAB suggests that more realistic ingestion rates and model parameters be considered. For example, the assumption that the subsistence fisher is the only fisher taking fish from the lake seems excessively protective. With some of the contaminants examined, fish will not take up 100% of the chemical. Likewise, 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 likely affect exposure estimates in the fisher population.

There is considerable heterogeneity in lakes. 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 as piscivores; benthic fish accounting for 17.5% and pelagic fish accounting for 3.5% of total fish biomass; humans consume 50:50% from benthic and pelagic piscivores (note some people 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) due to the general species abundance. At the same time, majority of POMs and dioxins partition preferentially to the sediments and benthic organisms are often enriched in pollutants compared to the water column species. Even when considering one trophic level difference, this does not account properly for ingestion exposure.

The SAB encourages the EPA to consider other data available to make more realistic assumptions such using as the most recent NHANES data to estimate fish consumption. Additionally, the EPA could refine the assumptions on chemical runoff and erosion from the watershed by using relevant USGS data that is available for the region in interest. This approach would result in a more balanced approach for tiers 2 and 3, since there are refinements in air modeling at these tiers.

The SAB struggled with understanding model inputs/assumptions. This process may become more transparent if the data are presented as a systematic review with elucidation of 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. Greater efforts to systematize transparency may reduce this uncertainty and confusion.

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 employed 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 and the most recent scientific paper cited by EPA on the TRIM.FaTE website was published. The authors of the Agency's draft RTR methods document may want to consult with EPA Office of Pesticide Programs (OPP) Environmental Fate and Effects Division (EFED) since they have developed models with different tiered assumption about runoff into ponds.

It is unclear how accurately PB-HAP deposition is calculated by such a simplified model. 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 to evaluate the implications of that accuracy for the reliability of fish consumption exposure estimates. EPA should test and demonstrate for a relevant range of representative scenarios the reliability of TRIM.FaTE air concentration and deposition estimates.

Finally, the SAB recommends conducting a probabilistic analysis of the distribution of critical parameters. The use of multiple health-protective assumptions/parameters is likely to overestimate the actual risks, probably by a substantial margin. Many parameters and assumptions appear to be methodological or based on EPA policy decisions. At times, it is unclear what is actually driving the model inputs. The probabilistic analysis should allow a more accurate and transparent estimate of the risks.

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 Agency undertakes an analysis following 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

(Section 3.3.1). The refinements also include analysis of plume rise resulting in PB-HAPs lost to the upper atmosphere (Section 3.3.2) and the use of time-series meteorology from meteorological data stations and modeled effective chemical release heights (Section 3.3.3).

Lake data

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. However, terms such as "accessible" should be carefully defined before being used in data analysis.

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 swampy lakes, which may host fish.

Plume rise

EPA could consider 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); documentation of AERMOD (Cimorelli *et al.* 2004) 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.

Escape of contaminants from the mixed layer

The SAB believes that the hour-by-hour response treatment is not yet justified for the following two reasons.

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 use of hour-by-hour data from the closest meteorological station. These data do not reflect specific microclimatic conditions at the site, including geological formation, directional valley orientations, and specific inversion conditions that can differ from those at the station. For accurate screening, these local conditions should be taken into account.

EPA could 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 cautions EPA to evaluate carefully the additional perceived accuracy proposed to result from implementing hour-by-hour adjustments in light of the time investment. 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.

The SAB recommends that EPA consider probabilistic analysis to determine the parameters and assumptions that most greatly affect predicted exposures. Identification of factors that dominate risk and uncertainty could guide future screening analyses by providing justification to obtain detailed input data for those factors. Probabilistic analysis could also assist in estimating 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 Agency methods (Section 3.4). The new pathway is a gardening exposure scenario added to the Tier 3 multipathway screen. The gardening exposure scenario is intended to better characterize multipathway risk for the Agency during its analysis. The Agency suggested this pathway 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 to Tier 3 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.

When considering the assumptions and approaches part of the Charge Question the first component addresses the media ingested by the Gardener. EPA has selected ingestion components similar to those experienced by subsistence farmers. These include direct ingestion of soil, ingestion of exposed fruits and vegetables, ingestion of protected fruits and vegetables and ingestion of root vegetables, and finally, 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 different categories that would afford coverage of the appropriate sources of soil ingestion and contaminants contained in soil. EPA presents a Table 3-17 distinguishing intake of Gardeners from Farmers by noting that meat products and dairy products are not likely to be sources for the Gardeners.

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 to the tiered approach. The SAB therefore suggests that it is especially important to distinguish between the Gardner and the Subsistence Farmer.

EPA has elected to separate Gardeners into two categories, Rural and Urban. The approach seems reasonable, especially given differing intake rates for Urban and Rural Gardeners. The assumption being that a rural Gardener would have enough land to develop a subsistence, or near-subsistence, garden, while the urban Gardener would not, seems, on the its face, to be valid. Following this reasoning, EPA has elected to use an upper (90^{th}) 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 ratios.) Both intake rates are taken from the Exposure Factors Handbook and appear to be justified as EPA's best assessment of such rates.

With regard to 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 latter is 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 facility, roadways, etc., and might well be considered important. The SAB suggests that these additional urban sources be considered and matched with those of the rural settings.

With the exception of 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 Gardner (See discussion below for both Adults and Children).

With regard to the second component of this charge question, it is clear that inclusion of the gardener scenario would afford improvement in characterization of the 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?

Chapter four of the Agency's draft RTR methods document describes the environmental risk screen used by the Agency to screen for potential adverse environmental effects associated with emissions of HAPs from facilities in the RTR source category being assessed. The screen's indicated design goals include minimal additional data gathering, and rapid application for robust and credible screening results. The attempt to achieve these goals relies on drawing from existing data, models, and modeling results, including those developed for the human health multipathway risk screen.

The revised environmental risk screen presented in the Agency's draft RTR methods document builds on and enhances the methods the SAB reviewed in 2009. The Agency included modeled environmental concentrations to compare with ecological benchmarks, in contrast to using human health thresholds, for all pollutants included in the screen. The revised methods apply systematic evaluation of HAPs for potential inclusion in the screen and the environmental risk screen was expanded to include additional environmental HAPs: cadmium, hydrogen fluoride, lead, arsenic, and additional POMs. The number of ecological endpoints and effect levels that we evaluated was also expanded. Additional Tiers were added to the environmental risk screen for PB-HAP that are parallel to the tiers in the multipathway screen.

Charge Question 6 addresses the information provided in Chapter Four 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 multipath way risk screen. The overall methodology was reviewed by the SAB in 2009. The material in Chapter Four 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 multipath way screen.

The SAB's findings and comments regarding the methodology are presented below. The SAB finds that the overall methodology and specifically the revisions since 2009 are reasonable 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).

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. The SAB is concerned that Selenium is not included as a chemical to screen. Given its potentially important role in ecological impacts we recommend that it be considered to be added to the list. In addition, it is not clear that BaP is the most appropriate chemical to use in the ecological analysis. There may be more important POM molecules (lower molecular weights) to use in this screening. Further analysis is recommended. In addition, the emission rates presented in Table 4.1 are for base year 2005. 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 that the expansion of the ecological assessment endpoints is reasonable and that the benchmarks, and the use of a tier system, are justified and a nice overall approach. The Agency's draft RTR methods document and appendices do a good job in documenting the processes and assumptions used to identify the endpoints and benchmarks. Overall the calculation of 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 Agency to continuously review and update them. Furthermore, many of the studies listed are from the 1980's - 1990's 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 notes that studies can be graded based on Klimisch score, a method of assessing the reliability of toxicological studies, mainly for regulatory purposes. Some additional text describing the reasoning behind the value chosen is recommended.

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 in TRIM.FaTE and encourages the advancement of the incorporation of AERMOD analysis within the TRIM.FaTE framework. The consideration of multi-source contributions to the soils is also recommended, though the SAB recognizes the Agency comment that inclusion of other industrial source categories in the analysis of risk in RTR screening analysis is prohibited. 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 implementing a probabilistic approach.

Furthermore, the receptors (i.e., organisms) may not be the best target organisms in specific cases so consideration should be given to add capability to modify in a site-specific manner. Finally, the SAB notes that analysis elements performed under the environmental risk screen may also be useful in the famer screen (e.g., utilizing the deposition to soils).

Additional Specific comments regarding endpoints and benchmarks include:

- The Agency could 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 (http://nadp.sws.uiuc.edu/committees/clad/) for the U.S. and the acidity associated with estimated chloride deposition could be compared to these critical load values.
- Hg 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 (e.g., song birds) (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/9781420084054)
(https://www.niehs.nih.gov/research/supported/assets/docs/a_c/bioscience_508.pdf)

- 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). To give an example, the sediment clean-up values for Onondaga Lake, NY, a mercury contaminated site are 2.2 µg/g for probable effective concentration based on macroinvertebrate toxicity testing and 0.8 µg/g for bioaccumulation based sediment quality. The Agency could 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 a number of contaminants.

3.7. Inhalation risk assessment enhancements

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 Agency 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 Agency 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 the dispersion of pollutants near sources.

The 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-based designation of "urban" based on population density ("HEM default procedure ") as the preferred method to make decision for each modeled site. The report rejects the use of the land cover method, citing that the comparison of the methods summarized in the Agency's draft RTR methods document show results that "matched well (about 90percent) with those made with the land use procedure or from application of the AERMOD Implementation Guide" and "in most cases where they did not match, the difference in modeled concentrations was small".

The SAB agrees that incorporating the effects of turbulence as a model input is appropriate and of significant value, as it avoids the overly conservative assumption of applying the "rural" assumption to all facilities, but the SAB disagrees with the Agency's draft RTR methods document on the procedure of choice. The National Land Cover Database (NLCD) land cover metric produced by the land use procedure best captures the intended characteristic - land cover characteristics that induce turbulence, and a more accurate model result provides better input for the next tier of risk assessment. 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 of using the HEM default procedure.

As reported in the results of the comparison between these two methods, the land use procedure identifies fewer areas as "urban" than the HEM default procedure (67 vs. 82); this is not surprising because these two approaches are measuring two different (but related) characteristics - land cover surfaces systemically sampled at a high (30m) spatial resolution, vs. population density which is measured at a much lower spatial resolution using non-random samples (census polygons).The Agency's draft RTR methods document notes that just over half of the facilities evaluated using these two methods qualify as "at least 50% urban", resulting in a difference in modeled concentrations using the two methods. However, the Agency's draft RTR methods document uses an arbitrary threshold of 20% difference in making its determination that the HEM default procedure is sufficiently accurate. Table 5-1 summarizes the results of testing these two procedures on petroleum refineries, with a column listing "percent difference in modeled concentrations", yet there is no entry for many of those facilities where the land use procedure would call for the "urban" specification. Two facilities on page 129 have no percent difference reported. The footnote explaining these missing values limits reporting only to those "clearly located in large urban areas". The meaning of this description and why it calls for no reported values for these facilities are both unclear.

The land use procedure directly measures the phenomenon 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, and little residential land. The land use procedure also more directly addresses EPA's 2005 Guidelines on Air Quality Models as stated on page 121 (last paragraph) in the Agency's draft RTR methods document, which lists 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 easily automated using ModelBuilder 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 are easily 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 inhalation risk assessment is a location-based estimate using modelled 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 that the latter misclassifies turbulence in some cases.

The SAB also noted that the quality of the NLCD data makes it possible to easily 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 variable value, and 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 modelling; 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 Agency 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. In fact, the differences in definition of these three NLCD classes is arbitrary, with thresholds at 80% and 50% impermeable land cover surfaces. 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 - 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.

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?

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. 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. In response the Agency developed the census block receptor enhancement (documented in Section 5.2 of the Agency’s draft RTR methods document) The Agency contends that the improvement allows for the modeling of air concentrations more accurately where populations actually reside. Specifically, the Agency suggests that the new enhancement automatically identifies census block centroids that might be located on-site at a facility being analyzed. The revised method is also expected to identify census blocks that are very large and hence analysis results may be questionable. When onsite or large blocks are identified, the revised method adds new

receptors, delete census block centroids, or moves census block centroids to represent residential locations. The goal is to develop a more accurate representation of receptors for analysis.

An enhancement that was made to the chronic inhalation risk assessment is the addition of the Census Block Receptor Check tool. The rational 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. The assumption is that the centroids represent a residential area, but this may not always hold true. The Census Block Receptor Check Tool was developed to address this concern. The 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 further 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 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 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 finds that the tool’s reliance on census block centroid locations is not sufficient to ensure that receptors are representative of residential areas near the facilities. One approach to address this problem would be to review satellite imagery within 1km 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 not reproducible between risk assessors. An alternative approach could employ 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 data population receptor placement is appropriate.

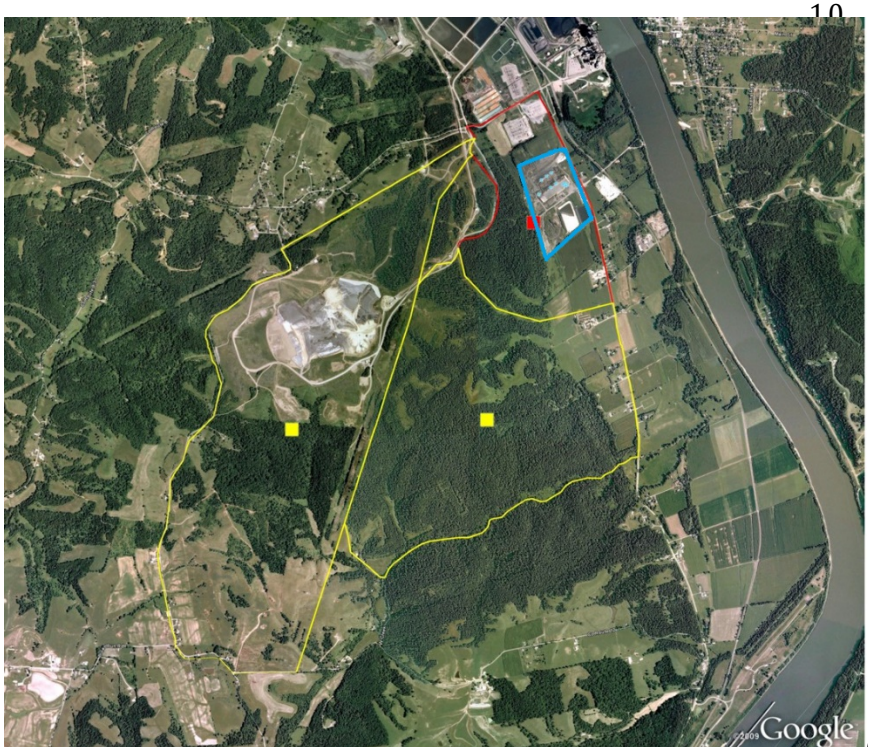

Figure 1. Use of polygon facility area for clipping receptor points in GIS
(satellite image from Google Earth™)

If the EPA prefers to continue using census block centroids as nearby exposure receptors, then the SAB suggests additional enhancements to make the tool less ad hoc. Facilities are better represented as polygons than points. Satellite imagery can be used to delineate the facility area and then GIS could easily exclude receptor points that were located within that area. Figure 1 shows the blue facility property outline with blue emission points, nearby blocks in red outline with the centroid as a red square intersecting the blue facility boundary, and large blocks in yellow outline with the centroid as a yellow square. For facility areas that do have an included census block centroid, then satellite imagery should be used for adding alternative receptors to replace the deleted centroid and ensure nearby residences are represented. It is worth noting that this would not be needed if receptors were placed at actual population locations as recommended previously.

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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/33152C83D29530F08525730D006C3A BF/$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)[2]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.

[2] Dioxins and Furans, Polycyclic Organic Matter, Mercury (Divalent and Methyl), Cadmium, Lead, and Arsenic.

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?