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"

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TO: Christopher Zarba, Director
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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/$File/ecadv05.pdf.

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

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

[1] 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?