UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: Request for SAB Peer Review of the "Report on the EPA's Risk and Technology Review (RTR) Risk Assessment Methodologies"

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This is to request a peer review by the Science Advisory Board on the draft document entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies". This document describes the Agency's methodologies for conducting baseline exposure and risk assessments for categories of industrial sources that emit hazardous air pollutants, highlighting the application of those methodologies with case studies on two source categories: petroleum refineries and Portland cement manufacturing. These source categories have previously been subjected to national emissions standards, and the purpose of characterizing risks now is to determine whether those emission standards (which were based on emission control technologies, work practices, and other control measures available at the time they were promulgated) are adequate to protect public health with an ample margin of safety and to prevent against an adverse environmental effect. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent an adverse environmental effect, EPA must develop standards to address these remaining risks. The Residual Risk section (112(f)(2)) of the Clean Air Act requires EPA to make these determinations for each source category through notice-and-comment rulemaking.

The risk assessment methodologies document was prepared by staff in the EPA's Office of Air and Radiation, and reviewed by staff in the Office of Research and Development and the Office of Policy, Economics, and Innovation. The document is being made publicly available on the Agency's website at the following URL: http://www.epa.gov/ttn/rrisk/RTR-SAB.

Attached is the draft of a charge to the Science Advisory Board that provides a background for the assessment and identifies the questions and issues we would like the Science Advisory Board to address in their peer review of the document.

Attachment

Peer Review Charge

EPA's Risk and Technology Review (RTR) Risk Assessment Methodologies

Case Studies -
MACT I Petroleum Refining Sources
Portland Cement Manufacturing

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

June 15, 2009

Overview

As part of our development of scientific support for rulemaking in the EPA's Risk and Technology Review (RTR) program, EPA is seeking input on whether our revised and expanded RTR risk assessment methodology is adequate to provide the basis for regulatory decisions concerning specific source categories.

The Clean Air Act establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAPs) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. We have largely completed these required initial "Maximum Achievable Control Technology" (MACT) standards. 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." In the second stage of the regulatory process, EPA is required to assess the health and environmental risks that remain after sources come into compliance with MACT. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, EPA must develop standards to address these remaining risks. This second stage of the regulatory process is known as the residual risk stage, or simply the "risk review." 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.

We have developed an RTR risk assessment process by which EPA: (1) conducts a risk assessment using currently-available source and emissions data; (2) shares the source and emissions data, along with a preliminary risk assessment, with the public through an Advance Notice of Proposed Rule Making (ANPRM) that requests public comments on the source and emissions data as well as any applicable data development methods; (3) reconciles comments and amends the source and emissions data as appropriate; and (4)

revises the risk assessment. The results of the revised risk assessment will support proposals and promulgations of technology- and risk-based regulatory decisions for each of the categories through notice-and-comment rulemaking process.

Previous Relevant Peer Reviews

In addition to the prior SAB panel consultation of December 2006, several previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. The present peer review is not intended to duplicate these previous efforts. 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 methods were described in this report, although individual elements have generally been improved over the techniques described in that document. (available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf)

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 similar to those for the planned RTR assessment.

3) The National Air Toxics Assessment, or NATA, for 1996 was peer-reviewed by an SAB panel in 2001-2002 (the SAB peer review report is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf). NATA 1996 was a comprehensive and cumulative risk assessment designed to include all mobile sources, small industrial sources, 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 recently-developed 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, we array several indices without prioritization. We are not asking the SAB panel to duplicate or comment on these previously reviewed dose-response assessments, but rather to evaluate whether we are using the most recent and appropriate, scientifically-credible dose-response approaches (as determined through previous peer review). 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. The final SAB advisory is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf.

Goals of This Review

Because RTR assessments will be used for regulatory purposes, and because they depart from earlier residual risk assessments in several important ways, we are seeking a scientific peer review of the assessment methodologies through the Agency's Science Advisory Board (SAB). A similar SAB panel provided a review of a residual risk assessment of lead smelters in 2000 and, more recently, provided a consultation on a summary of our proposed methodologies as they existed in December 2006. At that time we presented our proposed RTR assessment study plan to an SAB panel, which provided its formal consultation in a letter to us in June 2007. We have revised our process to incorporate many of the panel's suggestions, added significant new analyses and methods in some cases (*e.g.*, for assessing non-inhalation health risks and risks to ecological receptors), and developed risk assessments based on these changes. We are now requesting that the SAB provide a formal consensus peer review on the revised and expanded RTR risk assessment methodology.

In addition to describing this methodology, we present risk assessment case studies for the petroleum refining and Portland cement manufacturing source categories. These case studies are included to illustrate application of our risk assessment methodologies, which are the focus of this review. They are <u>not</u> actual residual risk assessments that may be used to support regulatory decisions, and the results of the case studies are not the focus of this review. The final assessments for these source categories will be published in conjunction with their respective final rulemakings. It is important to note that each of these case study examples represents a snapshot of an analysis which is at a different stage of development – the petroleum refinery case study has proceeded through the ANPRM stage as well as a Notice of Proposed Rulemaking (NPRM) stage but has not yet been issued in support of any final rulemaking. The Portland cement case study has not yet been issued through an ANPRM, and therefore has not yet been subjected to any public scrutiny.

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

1) A detailed screening protocol to determine if emissions of 14 persistent and bioaccumulative HAPs require a refined multipathway health assessment;

2) A refined multipathway health assessment methodology, shown for the Portland cement source category;

3) A refined ecological risk assessment methodology, shown for the Portland cement source category;

4) A screening analysis of potential foliar damage by direct contact with an airborne HAP (hydrogen chloride) for the Portland cement source category;

5) A methodology for showing the effect of long-term mobility on individual lifetime cancer risk estimates, shown for the petroleum refineries source category;

6) A methodology for refining acute exposure and risk estimates, shown for the petroleum refineries source category; and

7) An analysis of the effect of public comment on the health risk estimates, shown for the petroleum refineries source category.

While our charge questions below focus this particular peer review on these expanded aspects of our assessments as well as the results of various sensitivity studies conducted to inform our judgments on specific aspects of our assessments, we welcome inputs from the Panel on all aspects of our assessment methodologies and their application in each of the case studies.

Charge Questions:

There are eleven main charge questions for this peer review, each of which has been placed in a box below. These eleven questions concern seven topic areas that cover the major aspects of our risk assessment methodologies. Each of the charge questions contains a number of subquestions that are intended to serve as points or issues to consider when developing the response to the main question. As such, each subquestion does not require a direct answer from the peer review panel; we ask only that the panelists consider the subquestions as they develop the overall response to the main question. In addition, panelists should feel free to discuss aspects of the main question that are not covered by subquestions.

1. Revisions to emissions data:

As described in Section 2.2.1 of the Report (*i.e.*, the Petroleum Refineries case study), the 2002 National Emissions Inventory (NEI) serves as the starting point for RTR risk assessments. EPA performs an engineering review of data from each source category to identify and correct readily-apparent limitations and issues with the emissions data. The

dataset is then published through an Advanced Notice of Proposed Rulemaking (ANPRM), making it available for public comment. EPA evaluates comments and corrections for quality and engineering consistency, revises the dataset, and develops a draft risk assessment. The dataset and the risk assessment are provided with a Notice of Proposed Rulemaking (NPRM) for a second 60-day comment period, after which further comments and corrections are evaluated and incorporated. The final rulemaking is then developed. We have attempted to assess the quality of this process in three ways.

- Appendix A contains a comparison of risk estimates based on EPA's initial inventory as amended by engineering review and risk estimates based on the inventory as revised by public comment.

- Appendix L contains a comparison of modeled and monitored benzene concentrations around two petroleum refineries, with the intent of determining whether benzene emissions from refineries may have been underestimated at these facilities. The attachment to Appendix L provides an alternative view of this analysis and interpretation from an EPA staffer who reviewed this Appendix.

- Appendix P contains a comparison of petroleum refinery facility emissions estimates and facility risk estimates using the current RTR process to emission and risk estimates from the same facilities derived using a model plant approach based on generic emission factors. The goal of this analysis was to compare two different, but reasonable, sets of emissions estimates to examine the scope of uncertainty in the emissions data and the implications of these differences for estimated inhalation cancer risks.

Are the analyses performed in a scientifically credible manner and are the uncertainties and limitations adequately described? Do these comparisons provide useful information about the quality of the emissions data, and ultimately the risk estimates? Does the alternative viewpoint provided in as Attachment L-1 to Appendix L provide a better approach for analyzing and interpreting the monitoring data? Can you suggest improvements to these analyses, or others that might be more useful? Should we use these results to revise our risk assessment for petroleum refineries? Given that we have relatively high confidence about benzene emissions from refineries, can you suggest ways that we can develop similar analyses for other HAPs and source categories?

As described in Section 3.2.1 and Appendix F, we developed mean and upper confidence limit estimates for dioxins emitted from Portland cement facilities.

Does the approach used to estimate dioxin and furan emissions from Portland cement facilities represent the best available methodology in support of a risk analysis? Can you suggest improvements?

As described in Section 3.2.2 and Appendix G, we estimated potential emissions of radionuclides, and associated inhalation cancer risks, from two Portland cement facilities

using very limited data and three different derivations. The results vary by many orders of magnitude, but suggest that these risks could be substantial.

Is this approach rigorous enough to consider placing it in the RTR assessment, which has regulatory implications? If not, given the lack of reliable emissions data for radionuclides, how can we improve the approach? If the quality of emissions data remains an irreducible stumbling block, can you suggest ways to obtain better emissions data?

2. Dispersion modeling:

Section 2.2.2 describes our inputs to the AERMOD dispersion model for RTR assessments. We have performed the following analyses in an attempt to better understand the uncertainties and/or potential bias that may be introduced by some of these inputs:

- Section 4.4 compares exposure estimates based on one and five years of meteorological data.
- Section 4.5 presents an analysis of how the location of the meteorological station used for modeling affects the outcome.
- Section 4.6 presents an analysis of the effect on risk estimates of omitting atmospheric chemistry from the modeling of a high-impact refinery.
- Section 4.7 presents an analysis of the effect on risk estimates of omitting deposition from the modeling of Portland cement facilities.
- Section 4.8 and Appendix M present a sensitivity analysis of the uncertainties arising in the refineries assessment by estimating exposures at census block centroids rather than at the nearest residence.

Do these analyses adequately support the practices of (1) using a single year of meteorological data, (2) using facility-supplied meteorological data, when available, (3) omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling, and (5) using block centroids as surrogate exposure locations for these case studies? If so, can any or all of the analyses be applied to other source categories? If not, can you suggest ways we might improve them?

3. Dose-response assessment:

Section 2.2.6 of the Report describes our process of selecting and prioritizing dose-response values for RTR human health risk assessments. We select chronic dose-response values in the same way that we do for NATA, a process that the SAB has already reviewed in the context of NATA but not one of regulatory decision-making. We have also developed an analysis (presented in Appendix O) of the possible importance of HAPs that lack chronic dose-response values. This analysis suggests that only a few HAPs lacking such values

could be important, with the degree of importance heavily dependent on the conservatism of the input assumptions.

Is our process of selecting and prioritizing chronic dose-response values appropriate for RTR risk assessments? Should we consider additional sources, or a different prioritization process? Can the analysis of unassessed HAPs be improved by developing prior assumptions regarding the toxicity of these HAPs, and if so, how should this be done? Are there other ways we can improve it? Is this approach inherently limited to the current bounding exercise and tool for identifying research needs, or can it be further developed and incorporated into RTR assessments? Can you provide advice on how we can incorporate HAPs lacking dose-response values into our risk characterizations?

We developed our selection process for acute dose-response values more recently than the one for chronic values, and it has not yet undergone SAB review. The universe of acute health benchmarks contains many gaps, as shown in Table 2-5. In addition, some of the benchmarks correspond to "no-effect" levels (*e.g.*, CalEPA acute reference exposure levels, which are analogous to chronic RfCs), while others correspond to "mild-effect" or "severe-effect" levels (*e.g.*, acute exposure guideline levels) that are intended to guide authorities in making emergency evacuation decisions. For these reasons we have not applied a prioritization scheme.

We have not generally included acute minimum risk levels (MRLs, developed by the Agency for Toxic Substances and Disease Registry, or ATSDR) as dose-response values in our assessments of acute risks because of a temporal mismatch between the exposure estimates (based on one hour) and the MRLs (based on 24 hours to two weeks).

Given these gaps and inconsistencies among available acute benchmarks, do the case studies characterize acute risks adequately? Should we include ATSDR MRLs in our assessments, and if so, how can we solve the temporal mismatch? Is the use of emergency guidelines in our assessments adequately described and interpreted? Are there other acute health metrics EPA should consider using for these assessments? Do you have suggestions for improvements in any of these areas?

4. Chronic health assessment:

Section 2.2.3 describes the process by which we estimate chronic human inhalation exposures based on modeled average ambient concentrations at census block centroids. For these case studies, this process did not include consideration of either daily behavior pattern or long-term migration behavior. Section 2.2.3 presents a rationale for omitting daily behavior, and Appendix N presents a case study that adjusts inhalation-based lifetime cancer risk estimates for individuals to account for long-term migration.

Does our process of estimating inhalation exposures adequately support regulatory rulemaking? Is our rationale for omitting daily behavior convincing, or does the omission

compromise the value of our assessments? Should this, or some other, adjustment for long-term migration be incorporated into our risk assessments?

Appendix C describes a novel application of TRIM in the development of protective *de minimis* emission rates for 14 persistent and bioaccumulative HAPs (PB-HAPs). We believe that emissions below *de minimis* thresholds would not produce unacceptable risks in reasonable worst-case conditions. Facilities emitting below these values would not need to conduct a multipathway exposure and risk assessment.

Section 3.4 and Appendix I describe a refined application of the TRIM model in assessing multi-pathway pollutant transport and its subsequent impacts on human health from Portland cement facility air emissions identified as having a high potential to present significant impacts on human health.

We have limited our development of radionuclide risk estimates (described in Section 3.2.2 and Appendix G) to those associated with inhalation exposure. Radionuclides were not included in the multipathway risk assessment.

Is our use of the TRIM model to develop *de minimis* emission rates appropriate as a screening tool? Are the methodologies used in the refined multipathway assessment consistent with the best available science regarding multi-pathway pollutant transport and human exposures? Are the application of the model and the assumptions used clearly articulated? Are the resultant estimates of media concentrations and exposures clearly presented, explained, and interpreted? Given the large uncertainties surrounding the radionuclide inhalation assessment, are we justified in omitting radionuclides from the multipathway assessment?

5. Acute health assessment:

Section 2.2.5 describes our process for developing screening and refined estimates of acute inhalation risk. For acute screening purposes we have assumed that, in the worst case, a person could be exposed for one hour to ten times the highest hourly concentration calculated by the dispersion model. This in effect assumes a 1-hour emission rate of ten times the annual average (assuming continuous emissions), simultaneous occurrence of “worst-case” meteorological conditions, and also the presence of a person at this worst-case downwind location.

Appendix B presents an effort to evaluate the protectiveness of this screening assumption using detailed short-term emission data for a limited geographic area. Appendix E describes our refinement of acute risk estimates for refineries that failed the acute 10X screen, by using more accurate emission points and property boundaries.

Our refined acute assessments do not combine acute hazard quotients associated with different HAPs because of the inconsistent nature of acute health benchmarks and the inherent conservatism of our exposure assumptions.

Does the 10X acute screening assumption for petroleum refineries appear to be appropriately protective? If not, is it under- or over-protective? Given that this analysis applies only to sources in the Houston area, can we apply the 10X assumption to HAPs in other geographic areas, for other source categories, and for other HAPs, or should we consider some other approach for some other HAPs, *e.g.*, metals? Is there some other way we might address high emission events such as startup or shutdown of processes? Are the refinements to the acute screening assessment objectively employed and scientifically defensible? Should we sum acute hazard quotients by target organ in the same way we do for chronic hazard quotients, *i.e.*, a target organ specific hazard index (TOSHI) approach, or are our reasons for not doing so adequate?

6. Ecological assessment:

Section 3.5 and Appendix J describe a refined, site-specific application of TRIM to conduct an ecological risk assessment for PB-HAPs emitted by the same Portland cement facility evaluated in the human health risk assessment. Appendix J also describes a nationwide facility ranking exercise that identifies Portland cement facilities with the highest potential for causing indirect ecological effects via acidification of the environment by hydrogen chloride emissions. Appendix K describes an analysis of possible direct effects on plant foliage of air concentrations of hydrogen chloride emitted from Portland cement facilities that are below human health thresholds.

Is the ecological assessment case study scientifically defensible? Does it conform to EPA risk assessment guidance (*e.g.*, *Guidelines for Ecological Risk Assessment*, *Risk Characterization Handbook*, *etc.*)? If not, how can we improve it? Are the elements of the ranking scheme adequate to identify the facilities most likely to be of concern? Are there better data sources or approaches for drawing conclusions for specific locations? With regard to investigating the potential for direct ecological effects at air concentrations below human health thresholds from other sources or source categories, what suggestions can be made for prioritizing additional HAPs for literature searches similar to that done for hydrogen chloride in Appendix K?

7. Risk characterization:

The risk characterizations for these two case studies (Sections 2.3 and 3.6) represent our current practices in providing information to decision-makers responsible for RTR rulemaking. The analyses presented in the appendices are by and large illustrative of what can currently be done in the regulatory context, given time and resource constraints.

Do these characterizations objectively and completely incorporate the goals and principles of EPA's *Risk Characterization Handbook* to the extent scientifically feasible? In particular do they provide a complete and transparent discussion of uncertainties and limitations? If not, how can the risk characterizations be improved? Can you suggest where we might focus any additional efforts and resources in order to have the biggest impact on refining risk characterizations for these RTR assessments, ultimately leading to better regulatory decision-making?