UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

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OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

MEMORANDUM

SUBJECT: Request for SAB Consultation on the Risk and Technology Review (RTR) Assessment Plan

FROM: Steven D. Page, Director
Office of Air Quality Planning and Standards (C404-04)

TO: Sue Shallal, Ph.D
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400F)

This is to request a consultation by the Science Advisory Board on the draft document entitled, "Risk and Technology Review (RTR) Assessment Plan". This document describes the Agency's analytical plan for a set of risk assessments whose goal is to characterize the exposures and risks associated with the emissions of hazardous air pollutants (HAP) from 51 different industrial source categories. These categories have previously been subjected to national emission standards, and the purpose of characterizing their 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 adverse environmental effects. 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. The Residual Risk section (112(f)(2)) of the Clean Air Act (CAA) requires EPA to make this determination through notice-and-comment rulemaking.

The RTR Assessment Plan was prepared by staff in the EPA's Office of Air and Radiation, with significant assistance by staff in the Office of Research and Development, the Office of Policy, Economics, and Innovation, and the Office of General Counsel. The document is being made publicly available on the Agency's website at the following URL:
http://www.epa.gov/ttn/atw/rrisk/risk_technology_review_plan_sab_charge.zip.

Attached is a draft of a charge to the Science Advisory Board that provides a background for the assessment and identifies the questions and issues we want the Science Advisory Board to address in consulting on the document.

Attachment

Office of Air and Radiation
Risk and Technology Review (RTR) Assessment Plan
Peer Review Charge

Overview

As a part of the technical basis for rulemaking in the EPA's Risk and Technology Review (RTR) effort, EPA seeks input on whether its proposed RTR risk assessment methodology (emission data; dispersion and exposure modeling; risk characterization) is adequate to provide the basis for regulatory decisions concerning specific source categories. In sum, we are using a new approach to perform an assessment with the goal of characterizing the exposures and risks associated with the emissions of hazardous air pollutants (HAP) from 51 different industrial source categories. These categories have previously been subjected to national emission standards, and the purpose of characterizing their 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 adverse environmental effects. 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. The Residual Risk section (112(f)(2)) of the Clean Air Act (CAA) requires EPA to make this determination through notice-and-comment rulemaking.

The overall plan for the new approach is as follows: (1) conduct a risk assessment using currently-available source and emissions data; (2) share the source and emissions data and possibly the results of the assessment with the public through an Advance Notice of Proposed Rule Making (ANPRM) that asks for public comments on the analytical methods and the source and emissions data; (3) receive comments; (4) reconcile comments and correct the source and emissions data as appropriate, and; (5) reassess the risks. The results of the revised risk assessment will be used to support proposals and promulgations of technology- and risk-based regulatory decisions for each of the categories through the regular notice-and-comment rulemaking process.

Since the planned risk assessment represents a significant activity of an influential nature (*i.e.*, it will be used for regulatory purposes), and since it departs from previous risk assessments for the residual risk program in several important ways, we are seeking a scientific peer review of the assessment through the Agency's Science Advisory Board (SAB).

A background on the residual risk program and the regulatory decision framework associated with it is presented below to provide reviewers with a context for the assessment.

Background -- Regulatory Context and Decision Framework

Section 112(f)(2)(A) of the CAA requires EPA to evaluate whether previously adopted standards applicable to emissions of HAP from source categories under the technology-based (Maximum Achievable Control Technology, or MACT) program provide an ample margin of safety to protect public health and prevent adverse environmental effects, taking into consideration costs, energy, safety and other relevant factors. Any standards set under this section are to ensure that the public health is protected to a level which provides an "ample margin of safety" unless we determine that a more stringent standard is necessary after considering costs and other relevant factors. (We also recognize that emissions of persistent, bioaccumulative HAP (PB-HAP) may have an adverse environmental effect and need further evaluation beyond a human inhalation risk assessment. Source categories that emit PB-HAP will be addressed in the RTR III assessment.) The specific language of section 112(f)(2)(A) directs EPA to set additional standards through rulemaking if we determine that the MACT standards for the regulated source category do "not reduce the lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million..."

Risk assessments performed in the residual risk program are designed to generate answers to the questions posed by section 112(f)(2). Thus, the initial goal is to determine if previous standards do not reduce lifetime excess cancer risks to the individual most exposed to HAP emissions from a source in the category or subcategory to less than 1 in 1 million. In this context, the "individual most exposed" is an individual who has been determined to "live" in a census block that shows at least one resident in the 2000 Census. If a source presents lifetime excess cancer risk levels to this individual of 1 in 1 million or greater, then EPA must conduct rulemaking to ensure protection of public health with an ample margin of safety.

While the process for determining what constitutes an "ample margin of safety" was not explicitly specified in the 1990 CAA, section 112(f)(2)(B) expressly preserves the interpretation of "ample margin of safety" as it was used in the pre-1990 version of section 112 and as reflected in the 1989 "Benzene NESHAP." [1] In that rule, EPA explained that, "in protecting public health with an ample margin of safety ....., (we) strive to provide maximum feasible protection against cancer risks from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million and (2) limiting to no higher than approximately 1 in 10 thousand the estimated risk that a person living near a plant would have if they were exposed to the maximum pollutant concentrations for 70 years."[1]

In the approach used in the Benzene NESHAP, the first step of the two-step ample margin of safety framework is the determination of acceptability, i.e., the level of

[1] Rulemaking promulgating National Emissions Standards for Hazardous Air Pollutants for sources of benzene. 54 FR 38044, Sept. 14, 1989

cancer risks which can be considered "acceptable" based on health considerations only. (Costs, technical feasibility and other non-health-related factors are not considered at this stage.) The determination of an acceptable risk level is to be made in the context of "the world in which we live," that is, recognizing that our world is not risk-free. In the Benzene NESHAP, EPA determined that the cancer risk to the individual most exposed to emissions from the sources addressed in that rulemaking could not be considered acceptable unless it was at or below approximately 100 in a million (or 1 in 10,000). This determination established a "presumptive" acceptable level of 100 in a million cancer risk, thereby providing a benchmark for judging the acceptability of maximum individual risk for future risk-based emission standards, but not constituting a rigid line for making those judgments. (FR 38045, Sept. 14).

The second step of the ample margin of safety framework is the determination of what level of standard actually provides an ample margin of safety to protect public health. The maximum level of excess lifetime cancer risk associated with this standard can be no higher than what EPA determines to be the "acceptable" level for the particular category or subcategory, and it can be as low as or lower than approximately 1 in a million, but the ample margin of safety must be determined by balancing the costs associated with further reducing emissions against the health risk reductions achieved. To inform this judgment, residual risk assessments are designed to provide multiple metrics of risk (e.g., maximum individual risk, distribution of risks across the exposed population, total cancer incidence, noncancer hazard indices), as well as an indication of the limitations and uncertainties associated with the assessment.

Finally, to fulfill EPA's obligation under section 112(d)(6), every eight years we must review and revise as necessary (taking into account developments in practices, processes and control technologies) emission standards adopted under section 112. As recently explained in the notice of proposed residual risk rulemaking for the Hazardous Organic NESHAP (HON)[2], we view costs and risk as relevant factors in determining whether it is necessary to revise standards under section 112(d)(6).

Previous Relevant Peer Reviews

Several previous peer reviews have covered elements associated with this assessment or assessments with similar scopes or contexts. A peer review of this assessment is not intended to duplicate these previous efforts. A brief summary of each peer review is provided:

- 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 a peer review by the Agency's Science Advisory Board. Many of the design features of the RTR assessment were described in this report, although individual elements have generally been improved over the techniques described in that document.

[2] 71 (FR 34422, 34437; June 14, 2006)

- 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, Perchloroethylene Dry Cleaning, and Halogenated Solvent Cleaners. 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 which are similar to those for the planned RTR assessment.
- The National Air Toxics Assessment, or NATA, for 1996, was peer-reviewed by an SAB panel in 2002. While this assessment was a comprehensive and cumulative risk assessment (it was designed to include all mobile sources, small industrial sources, and large industrial sources, as well as background contributions of air toxics), because of the large amount of associated uncertainty it was deemed to be not appropriate for regulatory purposes, and it did not carry a census block-level resolution (it was performed at the census tract level). For this reason, on EPA's NATA web site the estimated risks are characterized as "starting points" for developing refined assessments.
- 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.
- Toxicity assessments – the individual dose-response metrics used in the RTR assessment have themselves been the subject of peer reviews through the agencies who developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry, and Environment Canada). EPA proposes to select dose-response values from these sources in the same priority order it used for NATA (i.e., IRIS, then ATSDR, then CA). 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 scientifically-credible dose-response approaches (as determined through previous peer review) and that, since environmental toxicology is continually evolving, this area is a source of significant, usually unquantifiable uncertainty.

Charge Questions for Peer Consultation

The peer consultation on the plan for the assessment will focus on: (1) the development of the source data and emissions inventory for the 51 source categories; and (2) the analytical approach for quantifying and characterizing human exposures and risks. In particular, we would like reviewers to consider the following questions as a means of focusing their consultation:

1. Scope: Is the scope of the assessment appropriate for the stated purpose? Is the overall approach clearly and adequately explained for review?

2. Emissions and Source Data: The NEI for hazardous air pollutants represents an ongoing voluntary national effort whose creation results from the collaborative efforts of State, local, and tribal air agencies with EPA Regional and Headquarters staff.
    a. Short of creating a federal mandate for reporting emissions to the EPA, do the methods by which the NEI was developed, reviewed, and compiled result in a technically-credible database that can support regulatory assessment and action? If not, can you suggest ways to improve it?
    b. Do the plans for conducting an engineering review and incorporating currently-available refined emissions and source data into the inventory add value to the assessment? Does the plan for soliciting public comment through an advanced notice of rulemaking add scientific credibility to the inventory? Is the plan for reconciling comments on the inventory adequate? If not, can you suggest other approaches for reconciling such comments?

3. Identifying Source Categories with Significant Non-inhalation Risk Potential: This assessment is only designed to include source categories whose risks are dominated by the inhalation pathway. Are the methods planned for selecting source categories with potentially significant ecological risks or multi-pathway human health risks for a separate, more refined ecological and multipathway assessment sufficiently health-protective? Are there ways that you might suggest for improving such screening techniques that can make them less conservative and still scientifically defensible?

4. Dispersion Modeling: Does the coupling of the AERMOD dispersion model with the census block human exposure modeling (HEM) approach to estimating individual and population exposures represent a credible approach for this goal? Are there other more credible approaches available for the estimation of inhalation risks from the types of source categories being examined? Is the level of accuracy of this approach acceptable for the purposes of residual risk decision-making? Are there any specific source categories, sources, or pollutants for which this approach might be considered inadequate?

5. Acute Exposure Screening: The plan describes a screening methodology for identifying potentially-significant acute exposures from routine emissions. Is this method appropriately protective? Can you suggest ways to refine the proposed acute exposure assessment process to enable it to support decision-making?

6. Exposure Assessment: Beyond the use of AERMOD-HEM, is the methodology planned for characterizing exposure commensurate with the needs of residual risk assessments? Specifically, do the underlying theory and data used to account for the effect of population migration on exposure make our lifetime population risk assessment more or less defensible than assuming that the exposed population lives in the same location for a lifetime of 70 years? Is omitting the attenuation of exposure concentrations associated with building penetration justifiable when

estimating lifetime risks for these chemicals and these types of sources? Is omitting the impact of short-term human activity patterns on exposures acceptable for these purposes?

7. Dose-Response Values: Is the plan for using available dose-response information (e.g., sources of information, prioritization scheme) appropriate for the purposes of this assessment? If not, can you suggest ways to improve it?

8. Risk Characterization: What are the strengths and the weaknesses of the overall conceptual approach to risk characterization planned for this assessment? Does the characterization plan adequately cover sensitive subpopulations and early-life exposures? Does the risk characterization plan appropriately aggregate cancer risks? Does the risk characterization plan appropriately aggregate noncancer risks? What are the strengths and weaknesses of the planned approach for characterizing important uncertainties, variabilities, and limitations? Given the underlying science and the intended purposes of the assessment, can you suggest ways that the characterization of uncertainty and variability could be improved, made more transparent, or integrated more effectively into the risk characterization?

9. Overall: Has any important scientific information been omitted from this assessment plan that could impact a subsequent regulatory decision? In your opinion, will the overall approach for the 51 source categories provide results that will be sufficient to support regulatory decision-making in the context of EPA's residual risk program?