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SCIENCE ADVISORY BOARD

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EPA-SAB-05-002

Honorable Michael O. Leavitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: EPA's Air Toxics Research Strategy and Air Toxics Multi-Year Plan – A Review by the Air Toxics Research Strategy and Multi-Year Plan Panel of the EPA Science Advisory Board

Dear Governor Leavitt:

Air Toxics are air pollutants that may pose a risk to human health or the environment. Hazardous air pollutants (HAPs) refer to the 188 air toxics that are subjected to regulations under section 112(b) of the Clean Air Act (CAA). The EPA Office of Research and Development (ORD), in consultation with the Office of Air and Radiation (OAR), developed an Air Toxics Research Strategy (ATRS) and an Air Toxics Multi-Year Plan (MYP) to help focus and set research priorities. The ATRS identifies air toxics research needs, while the MYP presents ORD's plan for addressing those needs in the 2003-2010 timeframe. This research provides scientific information and models to better understand the risks of air toxics and to help manage these risks.

An EPA Science Advisory Board (SAB) Review Panel was convened to review the Research Strategy and Multi-Year Plan. The Panel responded to five specific charge questions related to the ATRS, and four charge questions concerning the MYP. The Panel's review of these documents was significantly aided by interactive presentations and discussions with Office of Research and Development during its July 23-24, 2003 meeting. Detailed responses to each charge question are included in the Panel's report. The following are the Panel's key findings and recommendations:

- The Panel commends the Agency for its effort in developing the ATRS and MYP. Each document is well organized, logical, and of an appropriate level of detail. ORD is also commended for presenting the annual performance goals (APGs) and annual performance measures (APMs) in the MYP in terms of measurable outcomes and outputs for which the Agency will be accountable.

- The Panel found that there is a poor linkage between the ATRS and MYP because they follow two different and disconnected planning frameworks. The ATRS is built around five strategic principles, seven key research questions and many sub-questions. The MYP is organized around two long-term goals, APGs and APMs. The Panel is also concerned that the MYP's two long-term goals are too broad to provide useful guidance in setting research priorities. In addition, there is a need for both of these documents to clearly show their relationship with research strategies and multi-year plans in other EPA research program areas.

- EPA funding for air toxics research is approximately $20 M annually, of which approximately 20 percent is used for administration. The panel believes that this level of funding is inadequate, given the magnitude of research needs in this area, and the administrative costs are excessive. With the limited available funding, the ATRS cannot be accomplished without significant support from other EPA research programs. The Agency must be willing to reprogram funds among laboratories and centers as the need arises. In addition, the Panel underscores the need for EPA to articulate how it will coordinate and collaborate with other external research organizations.

- The Panel recommends that EPA set research priorities through a *transparent and open process* that emphasizes those HAPs that pose the greatest health risks to exposed human populations, based on exposure levels, size of the exposed population, and the severity of potential health effects. Although the ATRS lays out five strategic principles to guide and identify priority research activities, the MYP does not describe how these principles are applied in setting air toxics research priorities. In setting priorities, the Panel recommends that EPA use a tiered screening approach that progressively incorporates physicochemical, exposure, and biological data to identify chemicals that warrant additional research.

- The Agency utilized the National Research Council's 1983 (NRC 1983) risk assessment and risk management paradigm in developing its key scientific questions and strategic principles in the ATRS and long-term goals in the MYP. The SAB believes that EPA should employ an updated paradigm that emphasizes an integrated approach to the framing of the environmental problem, the technical risk assessment and risk characterization, the consideration of environmental decision options, and stakeholder involvement.

- The Panel noted that neither the ATRS nor the MYP addresses risk communication research. This is a significant omission. The Panel also identified several areas where greater research emphasis is needed, including:

- Improved ambient analytical methods for air toxics for use by EPA, States, and Tribes in improving monitoring networks and for validating models used to predict ambient concentrations of air toxics;

- Improved methods to characterize uncertainty and variability in exposure-response relationships and population distributions of exposure; and

- Studies of the risks associated with HAP mixtures in addition to single compounds.

o EPA should provide more opportunities for the external scientific community to contribute input on its air toxics research.

The Panel appreciates the opportunity to review these documents and feels that periodic involvement by a Science Advisory Board committee to review the strategy and annual plan components and to provide advice and feedback would be helpful to the Agency.

Sincerely,

/Signed/

Dr. William Glaze, Chair
US EPA Science Advisory Board

/Signed/

Dr. Frederick J. Miller, Chair
Air Toxics Research Strategy/
Multi-Year Plan Panel
US EPA Science Advisory Board

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Mr. Thomas Miller, Designated Federal Officer, Washington, DC

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Introduction

The EPA Office of Research and Development (ORD) conducts research to better understand and manage environmental risks. ORD, in consultation with the Office of Air and Radiation (OAR), developed an Air Toxics Research Strategy (ATRS) and an Air Toxics Multi-Year Plan (MYP) to help set research priorities. The purpose of the ATRS is to identify air toxics research needs, to support EPA's Strategic Goal 1: Clean Air. The ATRS is built around five strategic principles, seven key research questions and many sub-questions. The MYP presents ORD's plan for addressing those needs in the 2003-2010 timeframe. The MYP is organized around two long-term goals, annual performance goals (APGs) and annual performance measures (APMs).

An EPA Science Advisory Board (SAB) Review Panel was convened in response to ORD's request to review the ATRS and MYP. The SAB's review of these documents was significantly aided by interactive presentations and discussions with ORD during the Panel's July 23-24, 2003 meeting. This report presents the SAB's review of the ATRS and MYP, responding to five specific charge questions related to the ATRS, and four charge questions concerning the MYP.

General Comments

The SAB is pleased that the Agency is attempting to address long-term planning needs and to better integrate its research planning across ORD laboratories and office. Both the ATRS and MYP reflect these efforts, extending the planning horizon to 2010. The documents also convey EPA's consideration of the risk assessment paradigm in its air toxics research planning. In addition, the SAB commends ORD for presenting the annual performance goals (APGs) and annual performance measures (APMs) in the MYP in terms of measurable outcomes and outputs for which the Agency will be accountable. The SAB generally found each document well organized and of an appropriate level of detail. Neither the ATRS nor the MYP, however, achieves a sufficient level of planning integration to effectively inform research priorities. The SAB also found that there is a poor linkage between the ATRS and MYP because they follow two different and disconnected planning frameworks. In addition, the documents need to be updated to reflect events, documents, and research findings since the May 2002 ATRS External Review Draft.

The SAB believes that EPA's approximately $20 million annual funding for air toxics research is not adequate, given the magnitude of research needs in this area, and the Agency's 20 percent administrative costs are excessive. The Air Toxics MYP cannot be accomplished, therefore, without significant contributions from other EPA research programs. In addition, some air toxics research is funded outside of the air toxics research program. For example, while mercury and bioaccumulative toxins are hazardous air pollutants (HAPs), research for these are funded under EPA's Strategic Goal 4 (Health Communities and Ecosystems) because they are multimedia pollutants. As planning and management for these other research programs are largely independent of the air toxics research program, changes in their priorities and funding can have important but not immediately visible consequences for implementing the Air Toxics

MYP. The SAB recommends that EPA broaden its air toxics research planning and management to more fully integrate research that contribute to, but which are not organizationally controlled by, the air toxics research program. In addition, the SAB recommends that EPA develop a transparent accountability process for adjusting the allocation of air toxics research funding based on measurable research results.

The SAB underscores the need for EPA to articulate how it will integrate within EPA, and coordinate and collaborate with other research organization, to implement the Air Toxics MYP. The SAB recommends that the Air Toxics MYP clearly discuss and graphically illustrate the relationship with other research program multi-year plans, showing all research and funding that support ATRS implementation. Such a figure was shown by EPA staff at the review meeting, but was not included in either the draft ATRS or the MYP.

Finally, clearly defining and consistently using the terms "air toxics" and hazardous air pollutants (HAPs) can improve both the ATRS and MYP. At some places in the ATRS, "Air toxics" is used broadly whereas "HAPs" refers specifically to the Clean Air Act Amendments Section 112 list of 188 compounds. In other place in the ATRS and in the MYP, and during discussion with EPA, the terms are used interchangeably.

Response to the Charge Questions

The following comments summarize the SAB's response to the specific charge questions. A few additional comments on issues outside the specific charge questions are presented at the end. All comments must be considered together with the specific reports they address to be understood in their proper context.

Charge Question 1

1a. Does the research strategy provide a sufficient regulatory and research context?

Yes, the EPA's need for a strategic approach to air toxics research and the context for its application are well described.

1b. Is it on target in identifying and addressing the expected research needs of the air toxics regulatory program?

Not entirely. The research strategy identifies and addresses in general terms many of the research needs of the program in a comprehensive manner. The research strategy, however, does not set research priorities on those HAPS that pose the greatest risk to exposed populations. The SAB believes that there has been inadequate recognition that past and current EPA approaches for designating exposure-response relationships and population distributions of exposure implicitly incorporate a high level of uncertainty, making their suitability for the determination of credible residual risk levels for populations or for risk rankings uncertain. The ATRS should more explicitly focus on the development of methods to characterize uncertainty and variability in exposure-response relationships and distributions of exposed populations. These methods are

needed to better characterize potential risks to determine which HAPs warrant additional research.

The SAB recognizes that risks may be underestimated for certain chemicals or mixtures of chemicals where uncertainties are very large, for example, due to limited understanding of biological mechanisms, influence of co-exposure to other agents, and unknown but extreme variations of sensitivity between species and/or within segments of the human population. The SAB believes, however, that such underestimates of risk are rare. In consideration of the need for cost-effective means of reducing population risks from exposures to air toxics and for the setting of priorities for risk reduction activities, the program will best be served in the long-term by the application of improved methods for characterizing exposure-response relationships that explicitly account for uncertainty and variability, rather than overly investing in predictive toxicology.

1c. Is the primary purpose of the ATRS (of improving the science underlying the NATA Program) appropriate?

Yes. The purpose is highly appropriate. While the detailed refinements addressed in the ATRS are worthwhile objectives, they may not adequately address a critical long-term need: the development of methods to determine more accurate exposure-response relationships and that better characterize uncertainty and variability, as discussed in the SAB's response to charge question 1b.

Charge Question 2

Do the summary key questions and research needs comprehensively address the important research that should be undertaken, given the scope of the ATRS?

The application of the risk assessment paradigm to codify research needs for air toxics results in a relatively comprehensive list of important research activities that far exceed available Agency resources. The ATRS also provides five principles to guide Agency research decisions. The SAB does not believe, however, that these principles assist the Agency in priority-setting. Research priorities should be based on the magnitude of the risk and the need for greater certainty in risk assessment, such as captured in EPA's Principles 2 and 3 (ATRS, p. 27), and institutional factors such as in-house resources, research capacity, and knowledge of non-Agency organizations that may be better able to conduct the needed research. The SAB recommends developing questions or additions to the strategic principles to facilitate setting Agency research priorities. Examples of some questions to aid prioritization are:

- Is the research critical to reducing uncertainties before making a regulatory decision? Considerations should be given to:

    a. The results of epidemiological studies indicating elevated health risk and therefore warranting sufficient research to understand exposure-response relationships.

b. Other indicators of elevated risk, such as extent of exposure and potential cancer and non-cancer toxicity. When EPA RfDs and RfCs are not available, the Agency should consider using values from other organizations, e.g., California Proposition 65, Toxic Air Contaminants, and hazardous waste programs. EPA should also utilize new and/or updated RfDs/RfCs provided in draft assessments as a basis for identifying research priorities.

c. Extent of exposure to susceptible populations such as children, fetuses, or the elderly.

d. Extent to which populations exposed are disproportionately subjected to air toxics and other environmental risks due to economic disadvantage and other factors related to environmental justice.

e. Extent to which the risk is likely to increase or decrease in the future (for example, due to changes in the use of chemicals, changes in processes, or changes in emissions profiles).

- Is the public aware of the risk, or is there public concern? If the public were to be made aware, would there be concern?

- What is the potential for the research to have a significant impact on understanding the risk and affecting regulatory decision-making?

- Is the research anticipating a problem, and if conducted would it facilitate risk prevention and cost-effective environmental management? (See Science Advisory Board 2003:15, 19)

- Does the research address an orphan risk (e.g., from indoor air pollutants for which EPA lacks regulatory authority) from an important identified source of environmental exposure? (See Science Advisory Board 2003:4, 18-19)

- Does the research provide the greatest public health benefit for money spent? Is this research among the top priorities?

Examples of questions to address institutional factors in considering research priorities are:

- To what extent will the research support major upcoming rules and decisions?

- Is it essential for EPA to develop or maintain a core research capability, e.g., to anticipate the development of new science areas, and/or to continue core research as part of EPA's leadership role for specific Federal agency science activities?

- Does the research duplicate credible research being performed elsewhere? Are other Federal agencies doing significant research in this area? Could EPA provide sufficient input to ensure critical research performed elsewhere will meet Agency needs?

- To what extent can the research effort be used to leverage research being conducted elsewhere?

The ATRS does not adequately address the need for developing improved analytical methods for ambient monitoring of air toxics. While the need for additional research on improved analytical methods is acknowledged (Section 5 – Additional Research Desired), the SAB notes that currently available methods for air toxics are limited. For a number of the 188 HAPs, methods simply are not available. For other HAPs, current analytical sensitivity is poor. The problems with analytical methods severely limit understanding of ambient concentrations and spatial variability of air toxics. Improved analytical methods are necessary as EPA, States, and Tribes develop analytical monitoring networks and are necessary for validation of modeling used to predict ambient concentrations. Improved analytical methods would ultimately reduce uncertainty in risk assessment.

Given the limited funds available for air toxics research, EPA is encouraged to consider alternative avenues for addressing this research need, such as the Small Business Innovative Research (SBIR/STTR) and Science to Achieve Results (STAR) programs. External research funding to develop analytical tools and methods through the SBIR/STTR program may be an effective way to develop analytical tools, or at least significantly extend the capabilities of techniques under development at EPA. Additional leveraging of EPA air toxics research could be provided through the application of STAR program funds to support projects listed in Section 5 of the Air Toxics MYP, including fundamental studies on topics such as species' fate and transformation and risk assessment methodology. These avenues would have the benefit of leveraging the scarce ORD resources allocated to the study of air toxics.

The Agency utilized the National Research Council's 1983 (NRC 1983) risk assessment and risk management paradigm in developing its key scientific questions and strategic principles in the ATRS and long-term goals in the MYP. The SAB believes that EPA should employ an updated paradigm that emphasizes an integrated approach to the framing of the environmental problem, the technical risk assessment and risk characterization, the consideration of environmental decision options, and stakeholder involvement. Application of this paradigm would uncover research needs, address risks from airborne toxicants falling outside those of current regulatory focus, and would include research needs to support general risk management strategies. This would include research needed to:

- Maintain the HAPs list proactively, i.e., add to and remove chemicals from the list.

- Track non-regulated chemicals and sources of airborne pollutants for possible regulatory action.

- Understand the impact of risks from unregulated sources, such as off-road sources, ports, and certain consumer products.

- Assess the risks of mixtures.

- Assess behaviors critical to the management of airborne risks, particularly those from mobile sources and indoor air.

- Conduct research to support MACT.

Charge Question 3

Are all relevant discipline areas, e.g., emissions, exposure assessment, health effects, risk characterization, and risk management, addressed at an appropriate and consistent level of detail, thereby presenting a unified perspective?

The question was poorly formulated in that the conceptual framework for risk assessment used in the ATRS and MYP is that described in the National Research Council's 1983 "Red Book" (NRC 1983). As noted in our response to charge question 2, reference to the risk assessment/risk management (RA/RM) paradigm should be updated to include stakeholder input, including community concerns. Both stakeholder participation and risk communication are necessary parts of a comprehensive strategy. Neither Section 1.4 (Risk Assessment-Risk Management Framework for Air Toxics) nor Figure 4 (The RA-RM Framework) of the ATRS discusses or acknowledges the significance of stakeholder involvement. Research on how to accomplish stakeholder engagement, particularly in the risk management phase, appears warranted.

Similarly, the ATRS does not specifically address risk communication. SAB members felt this was a shortcoming of the research strategy. There is significant potential for misunderstanding and misinterpretation of the results of the risk assessment/management process. The SAB recommends that ORD address these issues in any revised ATRS or, at a minimum, consider these in their approach to reducing uncertainties in air toxics risk assessments (Multi-Year Plan Long-term Goal #1) and in implementing risk reduction of air toxics (Multi-Year Plan Long-term Goal #2).

Finally, the Presidential/Congressional Commission on Risk Assessment and Risk Management (Presidential Commission 1997) observed "it is time to modify the traditional approaches to assessing and reducing risks that have relied on a chemical-by-chemical, medium-by-medium, risk-by-risk strategy." The ATRS emphasizes the study of air pollutants one chemical at a time and delays the consideration of mixtures. There are advantages to beginning the study of mixtures now rather than later: regulated sources always emit mixtures, people always breathe mixtures.

Charge Question 4

4a. Are the strategic principles listed in Chapter 2 appropriate?

Yes. Collectively, the five Strategic Principles provide a guiding philosophy for the development and enactment of the ATRS. While the strategic principles are appropriate, discussion on what the principles actually represent relative to the ATRS is sometimes unclear or lacking. For example, Strategic Principle 2 establishes that the research and development activities will be focused on those air toxics for which risks are greatest to people and the environment. Table 5 gives the thirty-three pollutants on its Urban HAPs list, Table 6 gives twenty-one pollutants on its Mobile Source Air Toxics list, Table 7 gives eighteen pollutants on its Indoor Air Toxics list, and Table 8 gives fifty-four pollutants for stationary sources subject to early residual risk standards. In Table 9, there is a crosswalk of selected pollutants in terms of the four chemical structure HAP groups proposed in the ATRS. As discussed at several points in this SAB report, there should be a prioritization of the pollutants based on greatest risks to develop the most effective research strategy and multi-year research plan.

While one can hardly argue against the strategy reflected in Principle 2, the ATRS document does not provide much discussion about which factors to consider in establishing priorities. Uncertainty factors are emphasized as important for ranking compounds; however, projected human exposure levels, the number of exposed individuals, and the potential severity of response needs to be linked if any priority-setting process is going to address the concept espoused in Principle 2. As stated, Principle 2 should probably be the first strategic principle. For the current Principle 1, the concept of grouping is reasonable, but it would be better to refrain from referring to grouping by specific chemical class since there are a number of alternative grouping strategies that could be reasonably employed (see SAB's response to Charge Question 5).

4b. Do they facilitate effective decision-making for prioritizing future air toxics research?

The strategic principles have the potential to facilitate effective decision-making for prioritizing components of the research strategy. Currently, however, specific criteria and relative weights to be applied to each individual criterion are lacking. An effective strategy for such a large-scale program would benefit from a tiered approach. One should not assume that because little is known about a compound there is little risk for adverse health and ecological outcomes. Some minimal criteria for physico-chemical, potential population exposure (e.g., production volume, volume of formation, etc.), and biological data should be established as the first tier of information for prioritizing compounds for study. Criteria beyond the minimal set could provide a second tier for deciding whether additional information needs to be developed. Without a carefully prioritized and integrated research approach, EPA may spend large amounts of money and have little to show for it.

Charge Question 5

5a. Is the draft ATRS approach of grouping air toxics (Strategic Principle #1), first by chemical characteristics and then by regulatory need, appropriate, and what other approaches might be explored to efficiently group air toxics?

The grouping of air toxics by chemical characteristics and then by regulatory need appears to be a step backwards from what is already known about the risks associated with these substances. A narrow list of compounds has been identified on which EPA intends to focus. For example, EPA has designated an urban "Dirty 30" (actually 33 out of the 188) air toxics list based on, first, their presence in the human environment and, second, the toxicity of each chemical. In addition, the ATRS will not address all the pathways that introduce air toxics to humans and increase the predicted risk. The proposed grouping in the ATRS/MYP is less helpful than a grouping based on, for example, mode of action or relative toxicity of each substance, where data are available. In general, if a substance has both carcinogenic and noncarcinogenic modes-of-action, one can expect to reach the carcinogenic level of concern (e.g., a risk of 1 in 10^6) at a lower concentration than the noncarcinogenic level of concern (e.g., LOAEL or RfC).

The ATRS and the MYP should emphasize that grouping schemes, whether by physicochemical properties, toxicity, or mode-of-action, are ways of improving the efficiency of research planning to address specific questions and should not be confused with priority-setting. Setting priorities requires a separate process and, in general, the simultaneous consideration of more factors than does grouping. Different research questions may benefit from different ways of classification. For example, studies of environmental fate and transport may benefit from grouping by physico-chemical properties, while consideration and testing of emission control technologies might benefit from grouping by source. One must be cautious when grouping based on mode-of-action or toxicity because specific chemicals may have multiple modes-of-action or types of toxicity.

Many HAPs/air toxics, particularly those with multi-pathway routes, are being addressed in other research program MYPs. Consequently, the SAB had difficulty in determining whether certain classes of HAPs are receiving adequate coverage under the ATRS/MYP classification scheme. Metals are one such example. Metals are addressed in the Particulate Matter (PM) MYP, but the goals of the PM MYP are likely different (i.e., understanding transition metals and oxidative stress) from the air toxics MYP. In addition, the broad classification of metals together does not further their reclassification and prioritization on, for example, a biological basis. The mode-of-action and biological targets vary widely among the metals. It is therefore difficult for the SAB to answer the question as to whether the air toxics program is "comprehensive" without knowing what air toxics issues are also touched upon in the PM and other research program MYPs.

The most significant shortcoming of the current classification scheme is the inability to identify and address air toxics not included in Table 9, the "Crosswalk of Chemical Structure Groups and Priority Program Air Toxics." For example, "ground-truthing" exercises at the state or local/community level, which may identify new pollutants of concern, would not be addressed

by the current ATRS/MYP approach regardless of their risk level. At best, the scheme is at a level superficial enough (organics vs. inorganics) to incorporate newly found substances in the proper sub-classification, but it does not contribute to an understanding of their significance for potential community health risk (the responsibility of EPA).

The SAB recommends that the development of a priority research list of air toxics be iterative and open to modification, with clearly stated criteria for modification, addition to, or deletion from the list. The process must be able to accommodate a completely different approach as the state of the science evolves. An example is provided by the evolution of the National Priority List of the Superfund program: Superfund's Hazard Ranking System underwent significant changes as both science and evaluative methodologies improved. Such mechanisms for changes and improvements can be incorporated as appropriate, as determined either by ORD or in consultation with stakeholders.

5b. Does using the polycyclic organic matter (POM) example (Chapter 3) help explain the kind of research and development activities and project areas that should be expected as the ATRS is implemented, or should Chapter 3 be omitted because we now have an air toxics Multi-Year Plan (MYP)?

The POM example is reasonable to include in the ATRS. Since the ATRS predates the MYP by at least a year, there are significant mismatches between its structure, completeness, and the level of detail in the MYP. At a minimum, there should be an updating of that part of the ATRS to include cross-links to the MYP. The SAB recommends that the POM example be carried over from the ATRS to the MYP and re-cast to be closely tied to the elements of the MYP. The POM example is appropriate for both Air Toxics documents because of its suitability for illustrating a group of compounds (making allowance for additional specific substances that may emerge as substances of concern are added in more detail) whose primary pathway and exposure route of concern is air and inhalation. Thus, the class of POM substances is clearly part of the air toxics documentation; separate from other substances such as mercury and dioxins with more complex routes of exposure (and the subject of other, separate research program MYPs). A narrative about which major lines of research will be pursued by the Agency in examining POM would be a significant addition to the POM example and could help provide better linkage of the MYP to the ATRS. The SAB does not endorse the POM as necessarily the best example to use in the ATRS and the MYP (i.e., versus an example based on one of the other grouping categories). The SAB endorses, rather, the use of an example substance or class of substances to illustrate how the strategy and plan relate for one category of compounds.

Charge Question 6

Are the implementation approaches of developing an air toxics Multi-Year Plan, creation of a cross-laboratory and center air toxics steering committee, and conduct of scientist-to-scientist meetings on air toxics sufficient to implement the ATRS?

The implementation of the ATRS is to be accomplished by three methods: the Multi-Year Plan (MYP); cross-laboratory implementation committees; and scientist-to-scientist meetings.

All of these venues are reasonable approaches to developing and implementing the ATRS. The SAB offers the following comments to enhance these approaches.

If the MYP is meant to implement the ATRS, there must be obvious links between the two. This is not presently the case. The ATRS covers far more work than can be undertaken by the EPA, given budgetary limitations. Therefore, the MYP must clearly indicate what piece of the effort described in the ATRS the EPA will undertake. Where possible, the Air Toxics MYP should indicate the work expected to be undertaken by external research units such as academic laboratories and centers, private laboratories, and other government agencies. Mechanisms for EPA interaction with those external bodies should also be described.

Priorities need to be clearly stated in the ATRS and clearly addressed in the MYP. Such clarity is presently missing. The long-term goals of the MYP are so broad as to be almost meaningless. More focused goals related to the priorities developed in the ATRS would be much more useful.

The cross-laboratory implementation committees are essential to integrate the air toxics programs across all of the EPA programs and offices. The effectiveness of these committees will depend on the importance and support provided by upper level management.

The scientist-to-scientist meetings are also essential for efficient exchanges of information between science participants in the air toxics program. EPA management should offer opportunities for such exchanges on a regular basis. These exchanges can range from informal discussions in the local laboratory, to programmatic seminars, to national meetings across all program offices. For all of these exchanges it will be essential to include external scientists. EPA scientists have informal discussions with external scientists at major scientific meetings. For programmatic seminars, external scientists need to be invited as guest speakers. External guest speakers should always be a major part of national, across-program meetings.

Part of the implementation plan described in the ATRS states that individual compounds would be studied first, then by study of susceptible individuals, and followed by studies of mixtures. Thus, the recommended paradigm follows the traditional approach of looking at one toxicant at a time, despite the fact that sources always emit mixtures and people always inhale mixtures of pollutants. There are advantages to moving beyond the study of single components to the more relevant study of mixtures. One advantage is that regulatory measures can be applied to the mixtures emitted by some sources. Another is that health effects studies on source-related mixtures will provide more realistic data for use in risk assessment for public health than can be obtained by the study of single compounds. Hazard identification and dose-response assessments can be done in toxicity studies in animals exposed to the actual emitted mixtures, such as diesel exhaust, wood smoke, or coal combustion emissions. Emphasis should be placed on characterizing risks at low, environmentally relevant exposure levels. Such studies can provide more relevant health effects information than what can be obtained by studying single compounds or even binary mixtures.

There clearly are not sufficient funds to address adequately all of the individual Annual Performance Measures (APMs) that are part of the Multi-Year Plan. This makes it imperative that the Agency be willing to reprogram funds among laboratories as the need arises. For

example, if a proposed research avenue does not pan out, the resources should be shifted to another APM that may or may not reside within the same laboratory. As another example, the current budget allocation does not provide adequate resources for the proposed three to five community level exposure and epidemiology studies, and the RCT may well need to shift funds among laboratories to ensure that this high priority APM is accomplished.

Charge Question 7

As the MYP was developed, the intention was for it to reasonably follow from the ATRS. The foundation of the MYP is the two Long-Term Goals (LTGs). Thus, the segue from the ATRS to the LTGs should be seamless.

7a. Do the long-terms goals of the MYP align the ATRS, and do they support the priority needs of the program and regional offices?

7b. Would accomplishing these LTGs enable ORD to meet the Air Pollution Sub-Objective stated as follows: air toxics research will develop and improve air quality models and source receptor tools, cost-effective pollution prevention and other control options, and scientific information and tools to understand and characterize environmental outcomes associated with nationwide, urban, and residual air toxics risks?

This charge question was too broadly stated, as were the two LTGs developed in this MYP. Although the LTGs are aligned with the ATRS, it is difficult for this SAB to address this question without addressing the annual performance goals (APGs) and annual performance measures (APMs), which are addressed in the SAB's response to Charge Question 8. Consideration should be given to deleting such a broad charge question in future reviews.

There is not a seamless transition from the ATRS to the MYP. The ATRS is built around its five principles and its seven key research questions with their many sub-questions. The MYP is organized around its APGs and related APMs. Clearly, the research program envisioned in the ATRS is more encompassing than the MYP due to budget and other resource limitations. To make the segue from the ATRS to the MYP more transparent, it would be helpful in future Air Toxics MYPs to refer to the key ATRS question(s) being addressed in each APG and APM as is currently done in Chapter 3 of the ATRS.

Succinctly stated, LTG 1 is to reduce uncertainty in air toxics risk assessments and to conduct three to five community-level exposure and epidemiological studies to characterize the risk of air toxics. The first part is the overarching goal of much of the air toxics program. Conducting the three to five community-level exposure and epidemiological studies is a worthy goal, but it is less well developed in the MYP. There are no APGs or APMs that specifically schedule these studies that are to occur at the end of the MYP. Although the SAB considers these studies critical to the overall air toxics program, it concludes that under current funding levels there are not sufficient resources in the air toxics program to conduct these studies. Leveraging resources with funds from the Particulate Matter program or other resources within

the Agency will be essential to successfully conducting community-level exposure and epidemiological studies.

LTG2 calls for the production, by 2008, of 15 new or modified tools in the form of methods, models, or assessments that enable national, regional, or local officials to identify "cost-effective" approaches to reduce risks from air toxic sources. As stated, this goal is so vague that it will undoubtedly be achieved.

The SAB cannot adequately address whether the long-term goals of the MYP meet program and regional needs. They do support regulatory programs such as residual risk and seek to develop improved tools for evaluating air toxics. ORD representatives indicated that they were responsive to the needs of the clients, which are in this case the Office of Air and Radiation and EPA's regional offices. They indicated that they had consulted with an EPA regional representative in developing the MYP and were to meet on September 9–12, 2003, with EPA regional representatives on their air toxic needs.

Since the MYP has specific APMs for modifying the Community Multiscale Air Quality Model to allow modeling of some air toxics, it addresses the development of air quality modeling. On the other hand, the MYP does not have specific APMs that address the development of source-receptor models. Furthermore, the MYP does not have APMs that address effective pollution prevention and other control options beyond the development of tools. Reference to or coordination with the Pollution Prevention MYP could bolster the latter needs.

Charge Question 8

8a. Are the LTGs appropriate for meeting the Air Pollution Research Sub-Objective?

Referring back to the Air Toxics MYP Objective 1.5 on Science/Research, the goal of which is to provide methods, models, data, and assessment research through 2010, LTG1 would theoretically benefit from the promised advances in research. It must be noted, however, that the extent of the uncertainty reduction is unstated and we can only speculate about the credibility of the three to five studies to be performed with resources that are likely inadequate. As stated elsewhere in this review, if the EPA does not try to develop means for addressing uncertainty and variability in risk estimates (rather than conventional estimates), if the Agency does not provide sufficient resources to accomplish the studies in more than a superficial fashion, then LTG1, while achievable in the very general terms stated, could well be a waste of time and resources.

Regarding LTG2, the goal is also exceedingly broad, as we state in response to Charge Question 7. It is axiomatic that, at least for non-threshold pollutants, any reduction in source strength will lead to reductions in exposure and the health risks associated with exposure. For *de minimis* risks, however, it is not possible to identify cost-effective tools for the very small degrees of hypothetical risk reduction that might be achieved. For lifetime risks to the individual in the 10^{-4} to 10^{-6} range, the health benefits of source strength reduction would depend on the nature and severity of the health effect and the size of the exposed population. Furthermore, the

evaluation of the cost-effectiveness of source strength reduction would depend on, in addition to the inferred population risks, the credibility of the risk assessment. For most air toxics, risk estimates can be expected to remain highly uncertain in 2010 unless the program is reoriented soon to focus more explicitly on means to develop best estimates of exposure-response and population exposure distributions.

8b. Are the APGs and APMs measurable outcomes and outputs, respectively?

Table 6.0, describing APGs and APMs, is the most encouraging part of the MYP in that it briefly describes the specific tasks planned through 2010 and covers research that can fill many of the information gaps that have long limited EPA's ability to produce credible risk assessments. A reviewer comes away from an examination of this table with a high level of confidence that the exposure parameters and health effects of acute exposures to air toxics will be much better defined if this research is carried out. The tasks addressing the effects of chronic exposures represent generally appropriate and useful steps toward better risk assessment tools for chronic disease endpoints. They are reasonable choices in view of the limited research resources that are likely to be available in the 2003-2010 timeframe. Even with successful completion of these tasks, however, there will still be many information gaps left unfilled. Despite this caveat, EPA is to be commended for presenting the APMs in terms of measurable outcomes and outputs for which the Agency will be accountable. In any revision of the MYP, the SAB suggests that EPA:

1) Include year of initiation in listing of APMs and APGs and year of completion;

2) Provide alternative means of organizing APGs/APMs that are grouped by lines of inquiry (such a chart, if organized as a timeline, might take care of our first suggestion); and

3) Include in the Air Toxics MYP a section that reviews prior MYPs and summarizes successes, goals/objectives not accomplished, and changes made to the plan, and discusses reasons for changes.

8c. Do the APGs develop a critical path to achieve the LTGs?

The APGs are a logical and defensible subset of research goals that fit well into a strategic approach to the overall objectives of the Air Toxics program. They could be better organized, however, such as according to logical subsets of goals and their links to elements of the strategy. The APGs did not include one critically important area of research needed to make them a comprehensive program: information about the spatial variation of outdoor concentrations. This is of paramount importance in our efforts to assess human exposures to air toxics of ambient origin. In addition, outdoor concentration data are necessary for both the development and evaluation of source-to-receptor air quality models (e.g., ASPEN).

Considering the large spectrum of air toxics that need to be measured, development and operation of a comprehensive outdoor air-monitoring network will be prohibitively expensive. To overcome this problem, one can focus on chronic exposure assessments. Since we are especially concerned about cancer and other chronic disease outcomes, it will be highly

advantageous to develop sampling techniques for collecting long-term samples, e.g., seasonal and/or yearly specimens. This can be achieved using diffusion samplers or low flow samplers that operate intermittently, e.g., a few minutes per hour. Use of inexpensive sampling techniques for collecting long-term samples and their inherent advantages in terms of reduced number of samples for analysis by sensitive laboratory methods can make it possible to develop a comprehensive spatial network in a cost-effective way.

8d. Do the APMs encompass a body of research that "adds up" to logically achieve the APG?

Largely, they appear to, and ORD is commended for organizing this complex effort in an integrated manner. The specific tasks in the APMs need to be more clearly stated and should not be limited, however, as they were in this draft by a count of letter characters.

Charge Question 9

Are these resources sufficient to provide air toxics research that will achieve the LTGs and thereby support the regulatory needs mandated by the CAAA?

A clear indication as to how resource allocation decisions will be made among the research needs articulated in the ATRS and MYP is lacking. The SAB feels strongly that it is unlikely all topics identified in the ATRS can be addressed with the limited resources available to EPA. As previously discussed, there is a need for a clear strategy for setting research priorities. In the SAB's view, available resources are perhaps sufficient to achieve parts of the APGs and APMs that are listed in the MYP, but probably not to fulfill the regulatory needs as reflected in the long-term goals. There simply is not enough detail in the Air Toxics MYP to judge the scope of the proposed program relative to context or to available funding. The Air Toxics program is sorely under funded if the Agency is serious about achieving the long-term goals of the program. Of the 19.9 million dollars allocated as of mid-2003 for the ATRS, almost 20 percent is devoted to administration. This amount is not warranted, reflecting the bureaucracy of the Agency and implying that the actual allocation of FTEs for air toxics differs significantly from the FTE resources per the FY03 President's proposed budget.

To make inroads on the risk assessment needs, it would probably be better to address the unmet needs through the STAR program with a research grant Request for Application (RFA). The RFA should encourage grant submissions from risk assessors less bound by the conventional EPA risk assessment paradigm and who are willing to develop new methods to construct best estimates and address uncertainty and variability in risk.

Other Comments

SAB Panel members noted various issues that did not necessarily relate to a specific charge question but on which they wanted to convey their insight and feedback. These points are listed in the following bullets and are not in any order of relative priority or importance.

- The background should include some description of the origin of and recommendations made at the EPA SAB Workshop on the Benefits of Reductions in Exposure to Hazardous Air Pollutants: Developing Best Estimates of Dose-Response Functions, chaired by Dr. Michael Kleinman (Science Advisory Board 2002).

- Reducing uncertainty (LTG1) is a very important goal in terms of the credibility of EPA's science products generally; not only for the Air Toxics program determinations of residual risk. It is also critical to the Agency's needs for comparative risk assessments, cost-benefit analyses, and risk communication. For each of these important activities, there is a need for means of producing exposure-response relationships that take into account variability and uncertainty in preference to approaches currently used.

- The Research Coordination Team needs to be willing to reprogram across laboratory lines and not adopt an "everyone gets and keeps their piece of the pie" approach if the program is to remain integrated and responsive.

- Adding a section at the beginning of the Air Toxics MYP that provides an overview of various activities going on in other research program MYPs would be very helpful to readers and reviewers of the MYP. Such a section would help place into context the activities in the Air Toxics MYP.

- The SAB was pleased to see that exposure assessment is well addressed from both an ambient and indoor perspective. This reflects EPA's effort to be comprehensive in examining exposures.

- If other research programs MYPs are written at a similar level of detail as the Air Toxics MYP, a major aspect of an effective review of any Multi-Year Plan is the ability to have significant interaction with EPA staff during the review. Placing an emphasis on developing refined and focused charge questions will help a review panel in providing constructive feedback to the Agency.

- There should be periodic involvement by an SAB committee to review the strategy and annual plan components and to provide advice and feedback to the Agency.

References

NRC. 1983. "Risk Assessment in the Federal Government: Managing the Process." Washington, DC: National Academy Press.

Presidential Commission. 1997. "Risk Assessment and Risk Management in Regulatory Decision Making. Final Report of the Commission. Volume 2." Presidential/Congressional Commission on Risk Assessment and Risk Management.

Science Advisory Board. 2002. "Workshop on the Benefits of Reductions in Exposure to Hazardous Air Pollutants: Developing Best Estimates of Dose-Response Functions: An SAB Workshop Report of an EPA/SAB Workshop, EPA-SAB-EC-WKSHP-02-001." Pp. 18. Washington, DC: U.S. Environmental Protection Agency.

—. 2003. "Review of the FY2004 Science and Technology Budget Request for the U.S. Environmental Protection Agency: A Review by the U.S. EPA Science Advisory Board Science and Technology Review Panel, SAB-EC-03-006." Pp. 47. Washington, DC: U.S. Environmental Protection Agency.