CHAPTER 1 - PROJECT GOALS AND ANALYTIC SEQUENCE

Purpose and Goals of the Study

Section 812 of the Clean Air Act of 1990 requires EPA to perform periodic, comprehensive analyses of the total costs and total benefits of programs implemented pursuant to the Clean Air Act (CAA). The first analysis required under the Clean Air Act is a retrospective analysis, which EPA completed in October 1997. Section 812 also requires completion of a prospective cost-benefit analysis every two years. EPA completed the first of these prospective studies in November 1999.

This document represents the second step in EPA's development of a second prospective analysis of the Clean Air Act and Amendments of 1990: the development of a revised analytic plan and schedule for completing the study. In completing the second prospective, EPA is attempting to follow a process in which we seek a thorough review of our plans for conducting the study early in the process, incorporate review comments in a final analytic plan that incorporates the results of the review, complete the analytic steps in an expedited fashion consistent with the final plan, and then seek final review of the report and its results. EPA completed the first step in this process in July of 2001, when the SAB Council met to review a June 2001 draft analytical plan document. This final analytic plan document reflects significant revisions from the draft plan in response to: (1) SAB Council review comments finalized and delivered to EPA in September 2001; (2) the evolution of regulatory analytic practice at EPA over the last two years, including the establishment by OMB of Information Quality Guidelines for US Government reports and the adoption by EPA of its own set of guidelines; and (3) recommendations made to EPA by a special National Academy of Sciences (NAS) panel on the conduct of benefits analysis for air pollution. The NAS report in particular is the motivation for a major increased emphasis on the development of methods for characterizing uncertainty in benefit estimates developed for this report.

EPA continues to have four major goals for the second prospective:

1. ***Support CAA reauthorization and related legislative efforts.*** To achieve this goal, EPA has designed an analytic process that will provide a comprehensive accounting of CAA programs. To further this goal, EPA had originally proposed a Title-by-Title disaggregation of benefit and cost information. In response to SAB comments and discussion on this topic, we now plan to conduct disaggregation by major emitting source category (e.g., utility, non-utility industrial point source, mobile source), considering all applicable regulations regardless of Title. In addition, EPA still plans to assess costs and benefits of a limited set of additional measures that go beyond the current CAA provisions, although the nature of those additional measures has changed since the June 2001 draft plan. We hope these two sets of results will provide insight on the most cost-effective directions for potential future legislative efforts.

[continue on 1-2 – May 12 original]

Exhibit 2-6

Projection Scenario Summary by Major Sector in the Second Prospective

Sector	Pre-CAAA	Post-CAAA*	
Industrial Point	RACT held at 1990 levels	**NO_x**:	RACT for all NAAs (except NO_x waivers), NO_x measures included in ozone SIPs and SIP Call post-2000.
		VOC/HAP:	RACT for all NAAs, VOC measures included in ozone SIPs, 2-, 4-, 7-, and 10-year MACT standards, New control technique guidelines (CTGs).
		Ozone:	Rate-of-Progress (3 percent per year) requirements (further reductions in VOC).
Utility	RACT and New Source Review (NSR) held at 1990 levels. 250 ton Prevention of Significant Deterioration (PSD) and New Source Performance Standards (NSPS) held at 1990 levels.	**NO_x**:	RACT and NSR for all non-waived (NO_x waiver) NAAs, SIP Call post -2000, Phase II of the Ozone Transport Commission (OTC) NO_x memorandum of understanding, Title IV Phase I and Phase II limits for all boiler types, 250 ton PSD and NSPS, [text deleted] Additional measures to meet PM and ozone NAAQS.
		SO_x:	Title IV emission allowance program, [text deleted] Additional measures to meet revised PM NAAQS.
Non-road	Controls (engine standards) held at 1990 levels.	**NO_x**:	Federal Phase I and II compression ignition (CI) and spark ignition (SI) engine standards, Federal locomotive standards, Federal commercial marine vessel standards, Federal recreational marine vessel standards, NO_x measures included in ozone SIPs, Nonroad Diesel Rule.
		VOC/HAP:	Federal Phase I and II spark ignition (SI) engine standards, Federal recreational marine vessel standards. VOC measures included in ozone SIPs.
		CO:	Federal Phase I and II spark ignition (SI) engine standards. Category 3 marine diesel engines - proposed standards.
		PM:	Federal Phase I and II compression ignition (CI) engine standards, Federal Phase I and II spark ignition (SI) engine standards, Federal locomotive standards, Nonroad Diesel Rule.

- **Scenario 2** – On-highway vehicle NO_x and volatile organic compound (VOC) reductions. The specific control programs would include: (a) Tier 2 tailpipe standards applied nationwide,[1] (b) expansion of Federal reformulated gasoline to the entire Ozone Transport Assessment Group (OTAG) region, and (c) application of high enhanced inspection and maintenance (I/M) in metropolitan statistical areas and consolidated metropolitan statistical areas with 1990 population greater than 500,000.

- **Scenario 3** – This would include a combination of SO_2, NO_x, and VOC emission reductions from Scenarios 1 and 2.

In addition, EPA had previously planned to include alternative energy scenarios in its analysis of supplemental scenarios. In order to perform all of the disaggregated analyses necessary to meet the core objectives of the Section 812 study, however, EPA will need to exclude the analysis of alternative energy scenarios from the second prospective. EPA hopes to address alternative energy scenarios in future efforts.

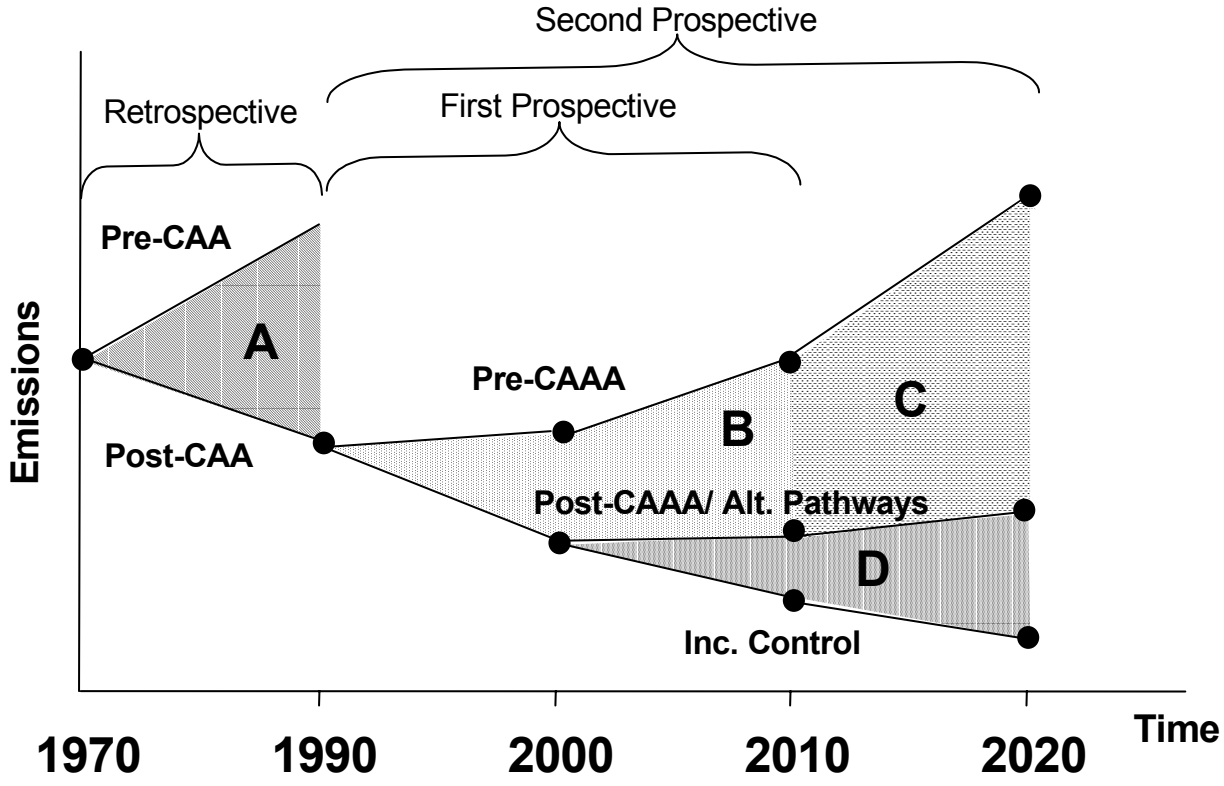
For the second prospective, EPA intends to analyze two types of supplemental scenarios: alternative pathway scenarios and increased control scenarios. For the alternative pathway analyses, EPA plans to assess the costs and benefits of different programatic pathways to core CAAA compliance. *These pathways represent a redistribution of emissions reductions across source categories*. As Exhibit 2-7 illustrates, alternative pathway emission reductions are intended to be comparable to post-CAAA emissions. [note: we probably can't make them exactly "equal" because of non-continuousness in the emissions control opportunity set.. This is discussed in more detail in another markup below...] Such an analysis will allow EPA to evaluate the relative efficiency of different strategies for complying with the CAAA. EPA also proposes to examine the costs and benefits of standards more stringent than those required by the CAAA. Area D in Exhibit 2-7 illustrates how an increased control scenario builds incrementally on the post-CAAA scenario. This analysis will provide insight into the potential implications of tightening CAAA requirements across source categories and pollutants.

EPA proposes the analysis of three alternative pathways. The first pathway emphasizes emissions reductions at utilities, with compensatory easing of reduction requirements from selected non-utility sources, resulting in overall progress toward NAAQS attainment comparable to that achieved by the core control scenario. The second scenario reflects a shift in NAAQS compliance strategies toward highway vehicles, and the last pathway combines elements of the first two. The pathways are as follows:

- **Pathway 1:** This pathway would reflect the electric generating unit cap and trade proposals included in the Clear Skies Initiative. These proposals include emissions caps of 3 million

[1] The Tier 2 tailpipe standards applied nationwide will now be applied in the post-CAAA baseline scenario, and will affect 2010 and 2020 emissions.

Exhibit 2-7: Comprehensive Schematic of Section 812 Scenarios and Emissions over Time



tons, 1.7 million tons, and 15 tons for SO_2, NO_x, and mercury respectively for the year 2018.[1] With this pathway's emphasis on emissions caps and allowance trading, other

control methods included in the post-CAAA scenario would be eased since they would not be necessary for core CAAA compliance.

C **Pathway 2:** The second pathway [text deleted] tightens NO_x and VOC emissions restrictions on motor vehicles while loosening CAAA standards for other source categories. The specific

[1] Additional information on the Clear Skies Initiative can be found on the EPA website: http://www.epa.gov/air/clearskies/basic.html#emissions.

control programs would include: (a) expansion of Federal reformulated gasoline to the entire Ozone Transport Assessment Group (OTAG) region, and (b) application of high enhanced inspection and maintenance (I/M) in metropolitan statistical areas and consolidated metropolitan statistical areas with 2000 population greater than 500,000. We are also exploring options to reflect additional measures beyond expanded reformulated gasoline and enhanced I/M programs as part of this scenario.

- **Pathway 3:** This pathway combines pathways 1 and 2 and eases other controls so that emissions remain at post-CAAA levels.

[text deleted]

Ideally, EPA's alternative pathways analysis would hold air quality constant to ensure that benefits remain constant across different pathways of compliance. Given increased emissions reductions for one source category, the ideal analysis would calculate the degree to which CAAA restrictions on other source categories would be eased in order to achieve air quality consistent with primary post-CAAA air quality. Based on the difference between primary and alternative emissions reductions, EPA could then estimate changes in compliance costs for each source category.

Unfortunately, EPA will not be able to follow this methodology for its assessment of alternative pathways in the second prospective. Estimating the changes in emissions reductions necessary to hold air quality constant would require feedback capabilities too cumbersome for available air quality models. Given an increased emphasis on emissions reductions for one source category, EPA would need to run several iterations of an air quality model to calculate the degree to which emission reductions from other sources could be eased while maintaining constant overall air quality. Although EPA could program an air quality model to perform such an analysis, model run time would be prohibitively long.

Given the infeasibility of holding air quality constant, EPA plans to hold emissions constant in its analysis of alternative pathway scenarios (though some slight variation in emission reductions between scenarios may prevail given the non-continuousness of emission control options). For the pathways emphasizing tighter controls on utilities, the decline in emissions from utilities will equal the increase in emissions from other sources. Similarly, for the pathways targeting motor vehicle emissions reductions, the extra decline in motor vehicle emissions will equal the increase in emissions from other sources. EPA recognizes that air quality, and therefore benefits, might change if emissions are simply redistributed among source categories. However, given the computational limitations of air quality modeling, emissions is the best variable around which to anchor an alternative pathway analysis since it is only one step removed from air quality in the 812 analytic sequence.

The second prospective will also consider increased control scenarios under which the Clean Air Act is made even more stringent by varying degrees, starting in the year 2000. Under these scenarios, emissions from all major source categories will continue to decline after 2000, instead of leveling off. EPA is still in the process of precisely defining the increased control scenarios.

Special Considerations for Mortality Concentration-Response

Epidemiological analyses have consistently linked air pollution, especially PM, with excess mortality. Although a number of uncertainties remain to be addressed by continued research (NRC, 1998), a substantial body of published scientific literature documents the correlation between elevated PM concentrations and increased mortality rates. Community epidemiological studies that have used both short-term and long-term exposures and response have been used to estimate PM/ mortality relationships. Short-term studies use a time-series approach to relate short-term (often day-to-day) changes in PM concentrations and changes in daily mortality rates up to several days after a period of elevated PM concentrations. Long-term studies examine the potential relationship between community-level PM exposures over multiple years and community-level annual mortality rates. Researchers have found statistically significant associations between PM and premature mortality using both types of studies. In general, the risk estimates based on the long-term exposure studies are larger than those derived from short-term studies. Cohort analyses are better able to capture the full public health impact of exposure to air pollution over time (Kunzli, 2001; NRC, 2002). The second 812 prospective study will estimate PM-related premature mortality benefits based on the full body of epidemiological literature, including both cohort analyses and short-term exposure studies.

Over a dozen studies have found significant associations between various measures of long-term exposure to PM and elevated rates of annual mortality, beginning with Lave and Seskin, 1977. Most of the published studies found positive (but not always statistically significant) associations with available PM indices such as total suspended particles (TSP). Studies of different fine particles components (i.e. sulfates), and fine particles, as well as exploration of alternative model specifications, sometimes found inconsistencies (e.g. Lipfert, 1989). These early "cross-sectional" studies (e.g. Lave and Seskin, 1977; Ozkaynak and Thurston, 1987) were criticized for a number of methodological limitations, particularly for inadequate control at the individual level for variables that are potentially important in causing mortality, such as wealth, smoking, and diet. More recently, several long-term studies have been published that use improved approaches and appear to be consistent with the earlier body of literature. These new "prospective cohort" studies reflect a significant improvement over the earlier work because they include individual-level information with respect to health status and residence. The most extensive study and analyses has been based on data from two prospective cohort groups, often referred to as the Harvard "Six-City study" (Dockery et al., 1993) and the "American Cancer Society or ACS study" (Pope et al., 1995); these studies have found consistent relationships between fine particle indicators and premature mortality across multiple locations in the U.S. A third major data set comes from the California based 7th Day Adventist Study (e.g. Abbey et al, 1999), which reported associations between long-term PM exposure and mortality in men. Results from this cohort, however, have been inconsistent and the air quality results are not geographically representative of most of the US. More recently, a cohort of adult male veterans diagnosed with hypertension has been examined (Lipfert et al., 2000). The characteristics of this group differ from the cohorts in the ACS, Six-Cities, and 7th Day Adventist studies with respect to income, race, and smoking status. Unlike previous long-term analyses, this study found some associations between mortality and ozone but found inconsistent results for PM indicators.

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Given their consistent results and broad geographic coverage, the Six-City and ACS data have been of particular importance in benefits analyses. The credibility of these two studies is further enhanced by the fact that they were subject to extensive reexamination and re-analysis by an independent team of scientific experts commissioned by the Health Effects Institute (Krewski et al., 2000). The final results of the re-analysis were then independently peer reviewed by a Special Panel of the HEI Health Review Committee. The results of these re-analyses confirmed and expanded those of the original investigators and identified concerns about the sensitivity and robustness of the findings, especially with respect to model specification. This intensive independent re-analysis effort was occasioned both by the importance of the original findings as well as concerns that the underlying individual health effects information has never been made publicly available.

The HEI re-examination lends credibility to the original studies as well as highlighting sensitivities concerning (a) the relative impact of various pollutants, (b) the potential role of education in mediating the association between pollution and mortality, and (c) the influence of spatial correlation modeling. Further confirmation and extension of the overall findings using more recent air quality and a longer follow up period for the ACS cohort was recently published in the Journal of the American Medical Association (Pope et al., 2002).

In developing and improving the methods for estimating and valuing the potential reductions in mortality risk over the years, EPA has consulted with a panel of the Science Advisory Board. That panel recommended use of long-term prospective cohort studies in estimating mortality risk reduction (EPA-SAB-COUNCIL-ADV-99-005, 1999). This recommendation has been confirmed by a recent report from the National Research Council, which stated that "it is essential to use the cohort studies in benefits analysis to capture all important effects from air pollution exposure (NRC, 2002, p. 108)." More specifically, the SAB recommended emphasis on the ACS study because it includes a much larger sample size and longer exposure interval, and covers more locations (e.g. 50 cities compared to the Six Cities Study) than other studies of its kind. As explained in the regulatory impact analysis for the Heavy-Duty Engine/Diesel Fuel rule (U.S. EPA, 2000a), more recent EPA benefits analyses have relied on an improved specification of the ACS cohort data that was developed in the HEI reanalysis (Krewski et al., 2000). The particular specification yielded a relative risk based on changes in mean levels of $PM_{2.5}$, as opposed to the specification in the original study, which reported a relative risk based on median levels[1]. The Krewski et al. analysis also includes a broader geographic scope than the original study (63 cities versus 50). Specifically, the relative risk from which the Base estimate derived is 1.12 per 24.5 : g/m^3 for all-cause mortality (Krewski, et al. 2000, Part II, page 173, Table 31). The SAB has recently agreed with EPA's selection of this specification for use in analyzing mortality benefits of PM reductions (EPA-SAB-COUNCIL-ADV-01-004, 2001).

[continue on 6-13 – June 26 revised]

[1]For policy analysis purposes, functions based on the mean air quality levels may be preferable to functions based on the median air quality levels because changes in the mean more accurately reflect changes in peak values than do changes in the median. Policies which affect peak PM days more than average PM days will result in a larger change in the mean than in the median. In these cases, all else being equal, C-R functions based on median $PM_{2.5}$ will lead to lower estimates of avoided incidences of premature mortality than C-R functions based on mean $PM_{2.5}$.

There are also several additional endpoints which the SAB recommended for evaluation and consideration during review of the first draft of this blueprint. Additional endpoints suggested for consideration which we plan to include in sensitivity analysis – but not in the primary quantitative benefit results – include (a) PM-related infant mortality and (b) ozone-related mortality.

The June 2001 draft analytical blueprint indicated EPA's intent to exclude PM-related post-neonatal infant mortality based on concerns expressed during a 1999 SAB review that the single available study (Woodruff et al.,1997) did not provide evidence adequate to support inclusion of this endpoint in the previous study.[1] However, in their September 2001 report reviewing the June 2001 draft blueprint for the current study (EPA-SAB-COUNCIL-ADV-004), the SAB cited new evidence reporting significant PM-related infant mortality including an eight-city study by Kaiser et al. (2001), Ha et al. (2001) in Seoul, and two others studies that relate PM_{10} to birthweight. Additional research is needed to explore these studies and how they might be incorporated into the second prospective study. We will provide the estimated effect of PM exposure on premature mortality in post neo-natal infants to show the specific impacts on an especially susceptible subpopulation. At this time, however, the estimates are not meant to be additive to the primary estimates of mortality.

We exclude ozone-related mortality from the primary analysis and include it as a sensitivity analysis because of concerns about double-counting the impact of PM and ozone on premature mortality as well as questions about ozone causality raised by the SAB. Additional research is needed to provide separate estimates of the effects for PM and ozone. To be conservative, we therefore include only the effect of PM on premature mortality in the primary analysis. We plan to explicitly address the uncertainty surrounding this endpoint, however, in our quantitative evaluations of uncertainty, as described in Chapter 9, and seek SAB input on the appropriate treatment for this endpoint.

Baseline Incidence

The baseline incidences for health outcomes we will use in the second prospective analysis are selected and adapted to match the specific populations studied. For example, we will use age- and county-specific baseline total mortality rates in the estimation of PM-related premature mortality. County-level incidence rates are not available for other endpoints. We will use national incidence rates whenever possible, because these data are most applicable to a national assessment of benefits. However, for some studies, the only available incidence information comes from the studies themselves; in these cases, incidence in the study population is assumed to represent typical incidence at the national level. Sources of baseline incidence rates are reported in Exhibit 6-2.

[continue on 6-14 – May 12 original]

[1] "3.5.2 PM Neonatal Mortality. HEES recommends that PM-related infant mortality data not be included in the analysis, without further supporting peer-reviewed published reports. The Agency must have an adequate data base (i.e., at least two or more peer-reviewed published reports) in order to derive a C-R coefficient. The current information does not support the use of neonatal mortality. Thus, neonatal mortality should not be included in the Prospective Study." (EPA-SAB-COUNCIL-DV-99-005, page 12).

Alternative Estimates

In addition to the Primary estimates of benefits, we plan to present one or more alternative estimates. For mortality incidence, at least one of the planned alternative estimates will assume that the effect is related only to short-term exposures or that any chronic effects are smaller in size than assumed in the Base Estimate. As a result, mortality incidence will involve the use of the Schwartz et al. (1996) short-term exposure study, adjusted using the ratio of distributed lag to single day coefficients from Schwartz et al. (2000). It does not incorporate any mortality effect of chronic-exposure. In addition, for at least one of the alternative estimates the project team plans to assume that death is advanced by six months for COPD-related mortality, and five years for all other causes.

The short-term mortality alternative(s) will provide an alternative perspective based on the life-expectancy method and will need to be considered in conjunction with the Base Estimate. Presentation of Base and Alternative estimates in the 812 Report may not be necessary if the probability analysis planned for the 812 Report is successful. Given the use of the Alternative, can the Council provide suggestions for improvement?

Sensitivity Calculations

In addition to the Primary and Alternative estimates of benefits, we present a series of sensitivity calculations that make use of other sources of concentration-response and valuation data for key benefits categories, as well as examining key analytical parameters, such as the form of the lag between changes in PM exposure and realization of changes in health outcomes. These estimates, however, are not meant to be comprehensive. Rather, they reflect some of the key issues identified by EPA or commentors as likely to have a significant impact on total benefits. Individual adjustments in the tables should not be added together without addressing potential issues of overlap and low joint probability among the endpoints. Exhibit 6-4 lists these sensitivity calculations.

[continue on 6-19 – May 12 original]

Exhibit 6-5
Alternative C-R Functions for Long-Term $PM_{2.5}$-Related Premature Mortality

Study	Mortality Category	Age	Pollutant	Metric
Pope et al. (2002)	All-cause	30+	$PM_{2.5}$	Annual Mean
Krewski et al. (2000) reanalysis of Pope et al. (1995)	All-cause	30+	$PM_{2.5}$	Annual Median
Krewski et al. (2000) reanalysis of Pope et al. (1995). Random effects, independent cities	All-cause	30+	$PM_{2.5}$	Annual Median
Krewski et al. (2000) reanalysis of Pope et al. (1995). Random effects, regional adjustment	All-cause	30+	$PM_{2.5}$	Annual Median
Pope et al. (2002)	All-cause	30+	$PM_{2.5}$	Annual Median
Krewski et al. (2000) reanalysis of Dockery et al. (1993)	All-cause	25+	$PM_{2.5}$	Annual Mean
Dockery et al. (1993)	All-cause	25+	$PM_{2.5}$	Annual Mean
Pope et al. (2002)	Cardiopulmonary	30+	$PM_{2.5}$	Annual Mean
Pope et al. (2002)	Lung Cancer	30+	$PM_{2.5}$	Annual Mean

Accounting for Potential Health Effect Thresholds

When conducting clinical (chamber) and epidemiological studies, C-R functions may be estimated with or without explicit thresholds. Air pollution levels below the threshold are assumed to have no associated adverse health effects. When a threshold is not assumed, as is often the case in epidemiological studies, any exposure level is assumed to pose a non-zero risk of response to at least one segment of the population.

The possible existence of an effect threshold is a very important scientific question and issue for policy analyses such as this one. The SAB Council has advised EPA that there is currently no scientific basis for selecting a threshold of 15 : g/m3 or any other specific threshold for the PM-related health effects considered in typical benefits analyses (EPA-SAB-Council-ADV-99-012, 1999). This is supported by the recent literature on health effects of PM exposure (Daniels et al., 2000; Pope, 2000; Rossi et al., 1999; Schwartz, 2000) which finds in most cases no evidence of a non-linear concentration-response relationship and certainly does not find a distinct threshold for health effects. The most recent draft of the EPA Air Quality Criteria for Particulate Matter (U.S. EPA, 2002) reports only one study, analyzing data from Phoenix, AZ, that reported even limited evidence suggestive of a possible threshold for PM2.5 (Smith et al., 2000).

Recent cohort analyses by the Health Effects Institute (Krewski et al., 2000) and Pope et al. (2002) provide additional evidence of a quasi-linear concentration-response relationship between long-term exposures to PM2.5 and mortality. The Executive Summary of the Reanalysis concludes: "They found some indications of both linear and nonlinear relationships, depending upon the analytic technique used, suggesting that the issue of concentration-response relationships deserves additional analysis. The Pope et al. (2002) analysis, which represented an extension to the Krewski et al. analysis, found that the concentration-response relationships relating PM2.5 and mortality "were not significantly different from linear associations."

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Daniels et al. (2000) examined the presence of threshold in PM10 concentration-response relationships for daily mortality using the largest 20 U.S. cities for 1987-1994. The results of their models suggest that the linear model was preferred over spline and threshold models. Thus, these results suggest that linear models without a threshold may well be appropriate for estimating the effects of PM10 on the types of mortality of main interest. Schwartz and Zanobetti (2000) investigated the presence of threshold by simulation and actual data analysis of 10 U.S. cities. In the analysis of real data from 10 cities, the combined concentration-response curve did not show evidence of a threshold in the PM10-mortality associations. Schwartz, Laden, and Zanobetti (2002) investigated thresholds by combining data on the PM2.5-mortality relationships for six cities and found an essentially linear relationship down to 2 : g/m3, which is at or below anthropogenic background in most areas. They also examined just traffic related particles and again found no evidence of a threshold. The Smith et al. (2000) study of associations between daily total mortality and PM2.5 and PM10-2.5 in Phoenix, AZ (during 1995-1997) also investigated the possibility of a threshold using a piecewise linear model and a cubic spline model. For both the piecewise linear and cubic spline models, the analysis suggested a threshold of around 20 to 25 : g/m3. However, the concentration-response curve for PM2.5 presented in this publication suggests more of a U- or V-shaped relationship than the usual "hockey stick" threshold relationship.

Based on the recent literature and advice from the SAB, our base assumption is that there are no thresholds for modeling health effects. Although not included in the primary analysis, the potential impact of a health effects threshold on avoided incidences of PM-related premature mortality will be explored as key sensitivity analysis, as noted above. Our assumptions regarding thresholds are supported by the National Research Council in its recent review of methods for estimating the public health benefits of air pollution regulations. In their review, the National Research Council concluded that there is no evidence for any departure from linearity in the observed range of exposure to PM10 or PM2.5, nor any indication of a threshold. They cite the weight of evidence available from both short and long term exposure models and the similar effects found in cities with low and high ambient concentrations of PM.

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CHAPTER 9 - UNCERTAINTY ANALYSIS

The second prospective analysis of the CAAA will provide a comprehensive economic analysis of air regulations using the best available methods and data. The cost and benefit estimates generated by this analysis will be uncertain, however, because of data and model limitations, measurement error, and the various modeling assumptions and choices necessary to implement such a complex and broad analysis. The identification and appropriate characterization of these uncertainties is an integral part of the second prospective analysis because it provides appropriate context for the results of this analysis.

This chapter presents our approach to characterizing uncertainty in the results of the second prospective analysis. This revised analytical plan reflects a significant new effort on the part of EPA to quantify previously unquantified uncertainties in the analysis, particularly in the areas of concentration-response uncertainties in the PM-premature mortality connection. This focus for the second prospective, along with other research investments in the process or planning stages, is a major component of the Agency's response to the National Academy of Sciences (NAS) recommendations to EPA concerning estimates of the benefits of air pollution. The Agency's plans are farthest along in the areas of critical concentration-response, but our plan for this study also includes initial efforts in the areas of cost, emissions, and air quality modeling uncertainties, as well as a commitment to follow-up on these initial analyses with subsequent research targeted on those parameters most critical to the overall conclusions.

This chapter consists of three parts. The first outlines how uncertainty was addressed in the first prospective. The second provides an overview of our plans for addressing uncertainty in the second prospective, including our revised approach to characterizing cost and benefit uncertainties. The last section presents a list of the major uncertainties from the first prospective and indicates the potential effect of our analytical plan for the second prospective on those uncertainties.

Review of Approach in First Prospective

EPA made use of four methods for characterizing uncertainty in the first prospective: probabilistic modeling; sensitivity tests; alternative paradigms; and qualitative characterizations.

Probabilistic Modeling

In the First Prospective, probabilistic analysis was used to model uncertainty in the human health effects of criteria pollutants and in the economic valuation of human health effects. For example, the value of a statistical life (VSL) input was based on analysis of results of 26 mortality risk valuation studies. In order to characterize uncertainty in this important input parameter, we

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initial efforts of phase one as pilot projects, it is important to recognize that we also intend to use the pilot results as they are available to guide other ongoing analyses, where possible. Phase two begins with a characterization of techniques used in the scientific community to estimate uncertainty. Then the phase two effort utilizes results from the pilot projects of phase one to investigate components of uncertainty in-depth.

The integration of plans for ongoing regulatory analyses with our plans for the Second Prospective introduces some additional challenges. Our plan also must be responsive to several key overall considerations. For example, EPA/OAR's current regulatory analysis methodology relies on a damage function approach that emphasizes state-of-the-art tools for analysis within each of four major disciplines: emissions estimation (demanding engineering expertise); air quality modeling (demanding advanced modeling of complex atmospheric chemistry and meteorology over mesoscale geographic spans); concentration-response assessment (demanding knowledge of epidemiologic and toxicologic assessment for human health, and ecological processes for environmental endpoints); and economics (with both cost-side and benefit-side sub-specialties). Understanding uncertainties requires a balance between advancing the state of knowledge within these analytic sub-disciplines, and moving ahead in a manner that recognizes the need to eventually treat quantified uncertainties in an integrated manner for the purposes of propagating uncertainty through to the primary analytic target: an estimate of net monetized benefits. Traditionally, there has been a focus on the former, with less emphasis on the latter.

There is a continuing need to focus on individual sub-disciplines, however, to ensure that decision-makers have the most accurate information and that EPA's regulations can stand up to challenge, and meet the rigorous demands of EPA's recent Information Quality Guidelines. In addition, effective uncertainty analysis demands emphasis on developing integrated tools for the purposes of propagating uncertainty from the initial steps (emissions and AQM) into an overall assessment of uncertainty in key analytic outputs (emissions, monetized costs, physical effects benefits, and monetized benefits).

EPA's response to these considerations has been to follow a carefully planned process for quantifying uncertainties across the full range of the analysis, beginning in late 2002, shortly after the publication of the NAS report in September 2002. Most recently, in April of 2003, the Agency convened a planning workshop meeting of EPA staff to establish objectives for the uncertainty analysis for the second prospective and develop plans for pilot projects that are consistent with an integrative analysis. That planning process is ongoing, but we have initiated efforts to characterize the key components of a benefit-cost analysis that influence uncertainty and we plan to initiate or continue five pilot projects (the pilots on PM C-R and mortality valuation had already been initiated by OAQPS to support the Nonroad Diesel and other rulemaking analyses):

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parameters. As an initial effort, however, we plan that the analysis be limited to quantifying uncertainty in engineering cost inputs and then assessing the impact of that uncertainty on the aggregate cost estimates.

1. **Emissions and Air Quality Modeling**. These two components of the analytic chain have likely represented a large source of unquantified uncertainty in past benefits estimates. Treating them as separate elements for the purposes of quantifying uncertainty, however, runs the risk that the resulting quantitative characterizations cannot be integrated without a very large commitment of time and resources. An alternative approach is being developed that will involve EPA experts working together to identify the major sources of uncertainty in these areas, and then working with a combination of off-line tools and formal and informal elicitation processes to develop a representation of uncertainty in emissions and, perhaps, key air chemistry calculations that can be used in downstream analyses.

2. **PM Mortality Concentration-Response**. This area has been a major concern of health impact analysts, both within and outside of EPA. The plan for this area includes an aggressively scheduled pilot project that involves a rigorously planned and executed expert elicitation. The main focus is to provide a broader representation of uncertainty surrounding the existence and magnitude of the relationship between acute and chronic exposure to PM and premature mortality, especially for use in national level health impact and economic benefits assessments. For the second 812 prospective study, we also will address the uncertainty associated with our understanding of the latency of PM-mortality effects as well as longevity for populations with PM-induced chronic illness. We have not yet defined our plan for looking at these aspects of the concentration-response function.

3. **Ozone Mortality C-R Function.** In addition, we are considering a second project that would explore the ozone-mortality concentration-response literature. Specifically, it is intended to address uncertainties in the developing literature concerning the impact of short-term (daily or over a few days) fluctuations in ambient ozone concentrations on mortality rates. Of particular concern is the existence of this effect independent of the effect of short-term $PM_{2.5}$ exposures.

4. **Mortality Valuation**. There are several existing analyses of the uncertainty in mortality valuation, including the empirical Bayes analysis of roughly 60 high-quality studies that is included in its pre-publication draft form as Appendix I of this document. Those analyses focus on measurement of uncertainty in the base VSL value and do not address key benefits transfer considerations for applying existing VSL estimates to the benefits of air quality improvements. The purpose of the pilot in this area is to integrate the results of the existing work with a representation of the "context" uncertainty. Ultimately, the goals of longer-term efforts over the course of the Second Prospective will be both to provide better information on how to appropriately integrate information from wage-risk and contingent valuation studies, and to value alternative outcomes from the PM Mortality C-R Pilot as necessary.

In the remainder of this section, we describe our plans for each of the efforts in more detail.

[continue on 9-8 – May 12 original]

rulemaking. It should also provide some of the background information needed for later uncertainty treatments. Equally important, Phase I will provide a basis for developing the more rigorous methods of Phase II. Phase II results are not expected to be available in time for use in the nonroad diesel final rulemaking but will be used by EPA in subsequent benefits analyses for other EPA air pollution rulemakings.

$PM_{2.5}$ Mortality Concentration-Response Function

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[text deleted]

To generate a technically sound approach to the elicitation and analysis of expert judgments about uncertainty in the PM2.5 concentration-response function, EPA is considering engaging analysts experienced in expert judgment elicitation. The following tasks outline the process we envision for completion of the pilot.

1. ***Defining elicitation scope and focus***: The first step will require that the elicitation analyst work with EPA staff responsible for the benefits analysis to define the specific questions to be answered. [text deleted] The goal of this step will be to make sure that the questions both serve the needs of the benefits assessment and are suitable for posing to experts. The elicitation analyst will also work closely with suitable "domain" experts in defining the approach.

2. ***Preparation of elicitation protocol***: The elicitation analyst will assist in the development of a technically sound and feasible elicitation protocol, based on the technical question, consideration of anticipated analysis of the judgments (e.g. distributional form, combination of the judgments), the phase of the project (pilot or longer-term analysis), and schedule.

3. ***Identification and Selection of Experts***: The elicitation analyst will guide the process for identifying and selecting a group of experts with relevant expertise to participate in study. The process should be transparent, using clearly defined selection criteria. EPA is considering using the two existing NAS panels that have recently examined the PM mortality literature and its application to PM health impact assessment, effectively building our initial expert selection upon the process employed by NAS. These two NAS panels, the Committee on Estimating the Health-risk-reduction Benefits of Proposed Air Pollution Regulations, and the Committee on Research Priorities for Airborne Particulate Matter, have members with established credentials in the subject matter area, and have already been selected by their peers as experts. In addition, the use of NAS panels as a source for expert elicitiation has been documented in peer-reviewed applications of expert elicitation.

4. ***Preparation of Briefing "Book"***: During an elicitation, standard materials are often made available to all experts involved in the form of a file or "briefing book". It may include a review of common pitfalls in giving subjective judgments, calibration exercises, as well as key papers or analyses relevant to the elicitation questions. The elicitation analyst, in collaboration with EPA and contractor staff, will develop a briefing book documenting key information pertinent to expert elicitation and the PM/chronic mortality issue.

5. ***Pilot Testing of Protocol***: Prior to conducting elicitations with the selected experts, the elicitation analyst will conduct pilot testing of the protocol with individuals having relevant expertise in the question(s) being elicited. The goal of the pilot testing will be to determine any changes needed to improve the clarity of the questions and/or the feasibility of the

[continue on 9-15 – May 12 original]

- G. Thurston and K. Ito. (New York University) Two-stage random-effects meta-analysis.

Each of the three groups has approached meta-analysis in a rigorous fashion, while using somewhat different methods. To ensure the robustness of the findings from meta-analyses of ozone-mortality relationships, this pilot will evaluate and characterize the findings from three independent research groups and methodologies. Results of this pilot will be distributions of the percent increase in daily all-cause and/or cause specific mortality associated with a 10 ppb decrease in daily one-hour maximum, or multi-hour average ozone.

In the case of the C-R function relating ozone and premature mortality, the meta-analytic approaches may be capable of characterizing certain elements of uncertainty, including sampling error and cross-location heterogeneity, but there are likely additional sources of uncertainty that should be characterized, including the influence of co-pollutants and biological plausibility of mortality impacts at relatively low ozone concentrations. These elements may need to be addressed through some subsequent use of expert elicitation methods. The outputs of the meta-analyses might be used as inputs to the expert elicitation process, providing a common base of empirical data for the experts to consider in making their probability judgments.

Valuation of Reductions in the Risk of Premature Death from Air Pollution

The third proposed pilot is intended to address the uncertainties surrounding the value of reductions in the risk of premature death from air pollution, commonly referred to as the value of a statistical life (VSL). Of particular concern is the uncertainty in transferring values revealed in the context of on-the-job risks (through hedonic wage-risk studies), which are based on working age individuals in a largely voluntary risk environment, to an air pollution risk context where at risk individuals tend to be older than the average age worker and the risks are largely involuntary. Additional sources of uncertainty include the relationship between remaining life expectancy and VSL and the impact of quality of life on values for fatal risk reductions. We are proposing a meta-regression analysis of existing VSL estimates in the economics literature and a more comprehensive examination of the VSL literature. As mentioned previously, EPA has sponsored reviews of this literature. We will also review other recent meta analyses discussed previously. We provide more details on the meta-regression analysis below.

Meta-regression Analysis: EPA has recently completed a meta-analysis of the VSL literature (Kochi, Hubbell, and Kramer, 2003). Does the SAB think that EPA should include Kochi et al. 2003 if not accepted for publication in a peer reviewed journal by the time the final 812 report is completed? As outlined in Chapter 8, the Kochi et al meta-analysis used empirical Bayes pooling methods to combine estimates from 40 wage-risk and stated preference studies into a single distribution, taking into account both within-study and between study variability. Pooled effect estimates of the kind generated by this type of meta-analysis can provide an improved central tendency estimate of VSL and a better estimate of variability around the central tendency, but do not systematically address or systematically eliminate between-study variability that may be associated with choice of estimation method and model, study location, target

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population, and demographic and risk characteristics (age, type of risk, etc.). Meta regression analysis has been widely applied in the health literature to pool results from clinical studies to examine how key factors influence health outcomes. In the economics literature, the approach has been used to examine determinants of willingness to pay for air quality improvement (Smith and Huang (1995) and Smith and Osborne (1996)) and determinants of VSL in hedonic wage studies (Mrozek and Taylor 2002).

Empirical Bayes meta-regression analysis uses a two stage hierarchical model to examine both within-study and between study variability. The first stage pooling completed by Kochi, Hubbell, and Kramer (2002) provides posterior estimates of VSL using information from all estimates in the literature. Additional work is necessary to provide further adjustment to the posterior estimates by specifying the VSL estimate as a function of study characteristics plus a between study variability term. The result of this analysis will be VSL distributions that are conditional on study characteristics. This will allow the analyst to calculate a VSL distribution that is appropriate to a given regulatory context. It will add to the growing literature on value of statistical life by systematically assessing that literature and shedding light on how study characteristics influence estimated VSL.

One specific issue highlighted by Kochi et al.is the finding that the stated preference VSLs are statistically different than the VSL estimates that are derived from the wage-risk studies. This raises the benefits transfer issues associated with this literature. In particular, are the wage-risk estimates (based on revealed preference) more reliable than the stated preference estimates for valuing these risk reductions. Or, are the stated preference estimates better for this benefits-transfer exercise?

Applying the Newly Quantified Uncertainties

With the results of the focused analyses described above in hand, we plan to use a similar approach to propagating and presenting uncertainties in benefits estimates associated with CAAA provisions as the approach we adopted for the first prospective analysis. For each of the three target years of the analysis (2000, 2010, and 2020) we will generate distributions of monetized annual estimates for the human health and welfare effects that incorporate both the quantified uncertainty associated with each of the health effect estimates and the quantified uncertainty associated with the corresponding economic valuation strategy. The resulting range of estimates for monetized benefits we present will be more narrow than would be expected with a complete accounting of the uncertainties in all analytical components.

In the first step of our procedure, we will employ statistical analysis to generate mean estimates and quantified uncertainty measures for each C-R function for each endpoint-pollutant combination. For the many health and welfare effects where only a single study is available to serve as the basis for the C-R function, we will use the reported estimate in the study as the best estimate of the mean of the distribution of C-R coefficients. We will characterize the uncertainty surrounding the estimate of the mean C-R coefficient by the standard error of the reported estimate. This yields a normal distribution, centered at the reported estimate of the mean. If multiple studies are considered for a given C-R function, we will derive a normal distribution for each study, centered at the mean estimate reported in the study (replaced in the case of PM-mortality by the results of the expert elicitation). On each iteration of the Monte Carlo aggregation procedure, a computer will select a C-R coefficient from an aggregate distribution of C-R estimates for that endpoint. The
[continue on 9-18 – May 12 original]

[The last row of Table 9-1 is deleted, so page 9-26 is deleted]

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Results of Uncertainty Analyses

In the June 2001 draft analytical plan, EPA proposed to present a summary form of the uncertainty analyses by presenting low and high estimates for benefits, net benefits, and the benefit/cost ratio. We proposed to present results in much the same format as the first prospective (see Table 11-2 below), in part to facilitate comparisons to the first prospective, but anticipated being able to provide entries for the low and high cost estimates, rather than leaving them blank as was done in the first prospective. In addition, we proposed to generate primary central, primary low, and primary high net benefits and benefit/cost ratio estimates with a probabilistic aggregation procedure, rather than the straightforward "ratio" calculation presented in the first prospective. In other words, we planned to develop a distribution of net benefits and benefit/cost ratios based on a Monte Carlo simulation of the subtraction of costs from benefits (for net benefits) or the division of benefits by costs (for the benefit/cost ratio). The 5th percentile of the resulting distributions would be the low estimate, and the 95th percentile would be the high estimate.

Our general strategy for presenting the results of uncertainty analyses is largely the same as in the June 2001 presentation, but we expect to be able to provide a more detailed and descriptive analysis of the results of the significantly enhanced uncertainty analyses proposed in Chapter 9. We hope that the enhanced uncertainty analysis will both provide a more comprehensive basis for characterizing uncertainty, and an ability to assess the likelihood of at least some of the alternative paradigm outcomes (e.g., alternative C-R specifications for PM mortality). We continue to anticipate a need to supplement the primary central results by calculating alternative estimates for some uncertainties that may not be addressed in the enhanced uncertainty analysis. One new calculation that will be presented along with the results of any alternative paradigm results is the QALY-based cost-effectiveness analysis results. Our proposed methodology for this analysis is described in Chapter 8.

The Agency has decided to include an alternative estimate until the formal probability analysis provides a better approach to characterizing the breadth of the uncertainty. Given the use of the Alternative, can the Council provide suggestions for improvement?

[continue on 11-8 – May 12 original]

CHAPTER 12 - PROJECT SCHEDULE

Exhibit 12-1 lists each of the key components and the currently anticipated completion date for that analytical step. The project schedule is predicated on EPA's plan to initiate analytical efforts immediately after the Summer 2003 SAB review meeting, following the methodological plans described in the 2003 analytical plan. We recognize, however, that these plans may be revised pursuant to SAB advice and by analytical issues and opportunities which emerge during study implementation (e.g., an option to employ a newly-released model or database, or new peer-reviewed effects literature).

EPA also anticipates requesting an in-progress review by the SAB in the December 2003 - January 2004 timeframe focused on (a) the interim results from the emissions and direct cost results, and (b) final methodological plans for the air quality modeling, physical effects, valuation, and uncertainty analyses.

Exhibit 12-1
Project Schedule

Component	Expected Completion
Analytical Design	Analytical plan: *June 2003*
Scenario Development	Scenario definitions: *August 2003*
Emissions Profiles	Emissions inventories for all scenarios: *November 2003*
Air Quality Modeling	Air quality modeling results: *February 2004*
Physical Effects Modeling	BenMAP health effect model results: *May 2004* HAP case study: *May 2004* Ecological case study: *May 2004* Title VI analysis: *May 2004*
Cost Estimation	Complete direct cost estimates: *December 2003* CGE modeling results: *July 2004*
Economic Valuation	Health effect valuation: Depending on how the Council and the EEAC can coordinate or conduct joint review: *June 2004* Welfare and ecological effect valuation: *April 2004*
Uncertainty Analysis and Results Aggregation	Cost-benefit results aggregation, uncertainty analysis, sensitivity analysis: *June 2004*

[continue on page 12-2 – June 26 revised]

Exhibit 12-1 **Project Schedule**	
Component	**Expected Completion**
Report Generation	Initial draft of Report to Congress: *August 2004* SAB review of initial draft Report to Congress: *October 2004* Publication of final Report to Congress: *December 2004*

[continue on first page or References – May 12 original]

SAB June 11-13 Review Charge Questions

May 12, 2003

This document conveys a set of specific charge questions which EPA respectfully requests that the SAB Council consider during its review of the May 12, 2003 draft analytical blueprint for the upcoming section 812 benefit-cost study of the Clean Air Act. The charge questions are organized by blueprint chapter or appendix. The first question posed for each chapter or appendix is intended to serve as a general charge question consistent with the statutory criteria for Council review of the section 812 studies.[1] Additional, more detailed charge questions are also conveyed for most chapters and appendices. These supplemental charge questions reflect EPA's desire to obtain specific and detailed advice from the Council on particular analytical issues.

Chapter 1: Project Goals and Analytical Sequence

1. Does the Council support the study goals, general analytical framework, disaggregation plan, analytical sequence, and general analytical refinements defined in chapter 1? If there are particular elements of these plans which the Council does not support, are there alternatives the Council recommends?

Chapter 2: Scenario Development

2. Does the Council support the choices for analytical scenarios defined in chapter 2? Are there alternative or additional scenarios the Council recommends EPA consider for inclusion in the analysis?

3. Does the Council support the alternative compliance pathway estimation and comparison methodology described in chapter 2, including the specification of alternative compliance pathways which may not reflect precisely constant emissions or air quality outcomes between scenarios due (primarily) to the non-continuous nature and interaction effects of emission control options?

[1] (g) The Council shall–
(1) review the data to be used for any analysis required under this section and make recommendations to the Administrator on the use of such data;
(2) review the methodology used to analyze such data and make recommendations to the Administrator on the use of such methodology; and
(3) prior to the issuance of a report required under subsection (d) or (e), review the findings of such report, and make recommendations to the Administrator concerning the validity and utility of such findings. [CAA §312(g)(1)-(3)]

Chapter 3: Emissions Estimation

4. Does the Council support the plans for estimating, evaluating, and reporting emissions changes as defined in chapter 3? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

5. Chapter 3 of the analytical plan describes several alternative approaches considered by EPA for estimating non-EGU emissions growth rates. These options reflect different relative emphasis between two conflicting analytical objectives: (1) extensive refinement of the geographically-differentiated, source-specific economic activity growth estimates embedded in EGAS 4.0, and (2) maintaining the current project schedule and budget. EPA plans to use "approach #4", a compromise option which targets the most important source categories for potential refinement. Does the Council support the initial plan to use "approach #4"? If the Council does not support the use of approach #4, are there other approaches –including either the approaches described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

6. Some state-supplied emissions data incorporated in the 1999 National Emissions Inventory (NEI) –the core emissions inventory for this analysis– incorporate different emissions factors from those used in MOBILE6, the mobile source emissions model EPA plans to use for estimating emissions changes between scenarios. Of particular importance, some of the emissions factors embedded in California's EMFAC model may be significantly different from factors used in MOBILE6. EPA considered three options for estimating emissions changes in California, which are described in chapter 3. EPA plans to implement option #3 based on the belief that the emission factors embedded by California in its EMFAC model may be more accurate for their particular state than the factors incorporated in MOBILE6. Does the Council support the plan to implement option #3? If the Council does not support the adoption of option #3, are there other options –including either the options described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

Chapter 4: Cost Estimates

7. Does the Council support the plans for estimating, evaluating, and reporting compliance costs described in chapter 4? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

8. EPA seeks advice from the Council concerning the choice of Computable General Equilibrium (CGE) model which EPA intends to use as a post-processor to gauge the general equilibrium effects of the various control scenarios. In the first 812 study –the retrospective– EPA used the Jorgenson/Wilcoxen model to gauge the general equilibrium effects of returning to the economy the reported compliance expenditures which formed the basis of the retrospective study direct cost estimates. This model has since been refined in many ways, and EPA considers both the Jorgenson/Wilcoxen/Ho and AMIGA to be acceptable tools. Although a final decision on model choice can be deferred until later in the analysis, EPA has tentative plans to use the AMIGA model because of its greater sectoral disaggregation, better industrial sector matching with CAA-

affected industries, richer representation of relevant production and consumption technologies, and better model validation opportunities due to its use of open code. Does the Council support the current, tentative plan to use the AMIGA model for this purpose? If not, are there alternative model choices or selection criteria the Council recommends?

9. In the two previous 812 studies, the primary cost estimates reflected use of a 5 percent real discount rate, which an earlier Council endorsed as a reasonable compromise between a 3 percent real rate considered by EPA to be most consistent with prevailing literature and a 7 percent rate based on the 1992 update of OMB's Circular A-94. The EPA-preferred 3 percent rate was, and is, designed to be consistent with a consumption rate of interest discounting concept, while the OMB-preferred 7 percent rate was, and is, intended to reflect the opportunity cost of private capital investment. Limited sensitivity testing was also conducted in the previous 812 studies by substituting –where possible– 3 and 7 percent rates to annualize the benefit and cost streams. EPA's new Economics Guidelines (peer-reviewed by the SAB EEAC) call for using a 2-3 percent rate consistent with the consumption rate of interest for primary analysis while acknowledging the need to also provide results based on a 7 percent rate as required by OMB Circular A-94. A recent draft of new OMB economic guidelines suggests providing results based on both 3 and 7 percent discount rates, while also acknowledging the need for further efforts to refine analytical policies for discounting methods and rates. EPA is concerned that presentation of multiple sets of "primary" results may breed unjustifiable confusion, particularly given the expected insensitivity of the overall results to the discount rate assumption. Therefore, EPA proposes to base the "primary" estimates on a 3 percent rate consistent with both prevailing peer-reviewed EPA Economic Guidelines, and to present these estimates as the principal results of the analysis. The 812 analysis would also conduct and present sensitivity tests using the OMB-prescribed 7 percent rate. Does the Council support this approach? If not, are there alternative rates, discounting concepts, methods, or results presentation approaches the Council recommends?

Chapter 5: Air Quality Modeling

10. Does the Council support the plans described in chapter 5 for estimating, evaluating, and reporting air quality changes associated with the analytical scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

Chapter 6: Human Health Effects Estimation

11. Does the Council support the plans described in chapter 6 for estimating, evaluating, and reporting changes in health effect outcomes between scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

12. EPA seeks advice from the Council regarding the technical and scientific merits of incorporating several new or revised endpoint treatments in the current analysis. These health effect endpoints include:

a. Premature mortality from particulate matter in adults 30 and over, PM (Krewski et al., 2000);

b. A PM premature mortality supplemental calculation for adults 30 and over using the Pope 2002 ACS follow-up study with regional controls;

c. Hospital admissions for all cardiovascular causes in adults 20-64, PM (Moolgavkar et al., 2000);

d. ER visits for asthma in children 0-18, PM (Norris et al., 1999);

e. Non-fatal heart attacks, adults over 30, PM (Peters et al., 2001);

f. School loss days, Ozone (Gilliland et al., 2001; Chen et al., 2000);

g. Hospital admissions for all respiratory causes in children under 2, Ozone (Burnett et al., 2001); and,

h. Revised sources for concentration-response functions for hospital admission for pneumonia, COPD, and total cardiovascular: Samet et al., 2000 (a PM10 study), to Lippmann et al., 2000 and Moolgavkar, 2000 (PM2.5 studies).

13. EPA seeks advice from the Council regarding the merits of applying updated data for baseline health effect incidences, prevalence rates, and other population characteristics as described in chapter 6. These updated incidence/prevalence data include:

a. Updated county-level mortality rates (all-cause, non-accidental, cardiopulmonary, lung cancer, COPD) from 1994-1996 to 1996-1998 using the CDC Wonder database;

b. Updated hospitalization rates from 1994 to 1999 and switched from national rates to regional rates using 1999 National Hospital Discharge Survey results;

c. Developed regional emergency room visit rates using results of the 2000 National Hospital Ambulatory Medical Care Survey;

d. Updated prevalence of asthma and chronic bronchitis to 1999 using results of the National Health Interview Survey (HIS), as reported by the American Lung Association (ALA), 2002;

e. Developed non-fatal heart attack incidence rates based on National Hospital Discharge Survey results;

f. Updated the national acute bronchitis incidence rate using HIS data as reported in ALA, 2002, Table 11;

g. Updated the work loss days rate using the 1996 HIS data, as reported in Adams, et al. 1999, Table 41;

h. Developed school absence rates using data from the National Center for Education Statistics and the 1996 HIS, as reported in Adams, et al., 1999, Table 46.

i. Developed baseline incidence rates for respiratory symptoms in asthmatics, based on epidemiological studies (Ostro et al. 2001; Vedal et al. 1998; Yu et al; 2000; McConnell et al., 1999; Pope et al., 1991).

14. EPA plans to initiate an expert elicitation process to develop a probability-based method for estimating changes in incidence of PM-related premature mortality. Plans for this expert elicitation are described in chapter 9 of this blueprint, and a separate charge question below requests advice from the Council pertaining to the merits of the design of this expert elicitation. EPA recognizes, however, the possibility that this expert elicitation process may not be fully successful and/or may not be completed in time to support the current 812 analysis. Therefore, in order to facilitate effective planning and execution of the early analytical steps which provide inputs to the concentration-response calculations, EPA seeks advice from the Council regarding the scientific merits of alternative methods for estimating the incidences of PM-related premature mortality, including advice pertaining to the most scientifically defensible choices for the following specific factors:

a. Use of cohort mortality studies, daily mortality studies, or some combination of the two types of studies

b. Selection of specific studies for estimating long-term and/or short-term mortality effects

c. Methods for addressing –either quantitatively or qualitatively– uncertain factors associated with the relevant concentration-response function(s), including

i. Shape of the PM mortality C-R function (e.g., existence of threshold),
ii. PM causality,
iii. PM component relative toxicity, and
iv. PM mortality effect cessation lag structure
v. Cause of death and underlying health conditions for individuals dying prematurely due to chronic and/or short term exposures to particulate matter

15. In two recent mobile source rulemaking analyses, two recent Title III MACT rulemaking analyses, and the benefits analysis for the Clear Skies Initiative, EPA included an "Alternative Estimate" in addition to a "Base Estimate" of total monetized benefits. The Alternative Estimates included in these five analyses differed in some respects, but in each case they reflected some combination of alternative assumptions regarding key factors in the estimation of PM-related benefits, particularly premature mortality and chronic bronchitis. Because these alternative estimates were motivated in part by the lack of a more fully developed probabilistic methodology able to incorporate the most important analytical uncertainties –and a more extensive probabilistic uncertainty analysis is planned for the current analysis– EPA plans not to incorporate an

Alternative Estimate similar to those adopted in the five recent EPA analyses. However, if the probability-based uncertainty analysis is not considered sufficiently extended by other federal agencies, there may be significant pressure on EPA to incorporate an Alternative Estimate similar, or identical, to those incorporated in the recent analyses. EPA seeks advice from the Council pertaining to the merits and utility of adding an Alternative Estimate similar to those incorporated in the five recent EPA analyses, either in addition to or in lieu of a probability-based uncertainty analysis. In addition to providing advice on the overall merit of using an Alternative Estimate approach, EPA seeks advice pertaining to the scientific and technical merit of three specific adjustments to EPA Primary Estimate methods incorporated in the recent Alternative Estimates, including:

a. Exclusive reliance on short-term mortality studies to estimate PM incidence changes (i.e., an assumption of zero effect from chronic exposure)

b. An assumption that a specific proportion of the PM-related premature mortality incidences are incurred by people with pre-existing Chronic Obstructive Pulmonary Disease (COPD) and that these incidences are associated with a loss of six months of life, regardless of age at death

c. An assumption that the non-COPD incidences of PM-related premature mortality are associated with a loss of five years of life, regardless of age at death

(Additional components of the Alternative Estimate, including differences in valuation method, are addressed in a separate charge question below.)

Chapter 7: Ecological Effects

16. Does the Council support the plans described in chapter 7 for (a) qualitative characterization of the ecological effects of Clean Air Act-related air pollutants, (b) an expanded literature review, and (c) a quantitative, ecosystem-level case study of ecological service flow benefits? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

17. Initial plans described in chapter 7 reflect a preliminary EPA decision to base the ecological benefits case study on Waquoit Bay in Massachusetts. Does the Council support these plans? If the Council does not support these specific plans, are there alternative case study designs the Council recommends?

18. Does the Council support the plan for a feasibility analysis for a hedonic property study for valuing the effects of nitrogen deposition/eutrophication effects in the Chesapeake Bay region, with the idea that these results might complement the Waquoit Bay analysis?

Chapter 8: Economic Valuation

19. Does the Council support the plans described in chapter 8 for economic valuation of changes in outcomes between the scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

20. Pursuant to SAB Council advice from the review of the first draft analytical blueprint, EPA reviewed a number of meta-analyses –either completed or underway– developed to provide estimates for the value of statistical life (VSL) to be applied in the current study. EPA plans to use VSL estimates from the Kochi et al (2002) meta-analysis to generate the primary benefits estimates for this study. In addition, EPA plans to implement two particular adjustments to the core VSL value from Kochi et al (2002): discounting of lagged effects and longitudinal adjustment to reflect changes in aggregate income. Does the Council support these plans, including the specific plans for the adjustments described in chapter 8? If the Council does not support these plans, are there alternative data or methods the Council recommends?

21. As described in charge question 15, EPA has recently incorporated an Alternative Estimate of benefits in several recent Office of Air and Radiation analyses. In addition to the alternative assumptions related to health effects estimation described in charge question 15, the Alternative Estimates in these analyses applied methods or assumptions for economic valuation which differ significantly from approaches used by EPA to generate base estimates. EPA seeks advice pertaining to the scientific and technical merit of four adjustments to EPA Primary Estimate methods incorporated in the recent Alternative Estimates, including:

    a. An initial VSL derived by using only five contingent valuation (CV) studies from the larger set of 26 hedonic wage and CV studies used to generate Primary Estimates in the previous 812 studies

    b. Age-based adjustment to the CV-based VSL estimate described above using Jones-Lee (1989) –but not Jones-Lee (1993)– which had the practical effect of reducing initial VSL for people aged 70 and above by 37 percent [note: this was the approach used for the recreational vehicle and the Clear Skies Initiative analyses, but not the most recent analysis of the proposed nonroad diesel vehicle rule]

    c. Age-based adjustment to the CV-based VSL estimate described above using a statistical life-years approach which assumed that later life-years may have a higher per-year value than average life-years saved in the middle of the life span [note: this was the approach used in the analysis of the proposed nonroad diesel vehicle rule]

    d. Use of a cost of illness estimate based on Cropper and Krupnick (1990) to estimate the value of avoided chronic bronchitis, rather than the willingness to pay estimates used to generate Primary benefit estimates in the previous 812 studies

22. Does the Council support the derivation of VSLY values based on the life expectancy of the general population for application to individual loss of life years in individuals with greatly

reduced life expectancy relative to the general population? If the Council does not support this approach, are there any life years-based valuation methods that the Council finds to be consistent with a standard welfare economics-based cost-benefit analysis?

23. EPA plans to use updated unit values for a number of morbidity effects, as described in chapter 8. Of particular note, EPA plans to rely on a study by Dickie and Ulery (2002) to provide heretofore unavailable estimates of parental willingness to pay to avoid respiratory symptoms in their children. This study is not yet published; however, EPA expects the study to be published prior to completion of the economic valuation phase of this analysis. Does the Council support the application of unit values from this study, contingent on its acceptance for publication in a peer-reviewed journal? If the Council does not support reliance on this study, are there other data or methods for valuation of respiratory symptoms in children which the Council recommends?

24. In the previous prospective 812 study and in the June 2001 draft blueprint for the current study, EPA expressed a preference not to report results in terms of QALY-based cost-effectiveness. This preference was motivated primarily by (1) the lack of generally accepted data and methods applicable to QALY computation in an air pollution context, (2) potential biases in the implicit cost-effectiveness results caused by incomplete netting out of other health and ecological benefits from the numerator, (3) concerns about the distortionary effect of the simplifying assumptions pertaining to time and quality trade-offs required to estimate QALYs, and (4) the general disconnect between available QALY methodologies and standard economic utility theory. In addition, EPA is seriously concerned about the requirement imposed by the QALY methodology to assign lower values to the lives, and the quality of the lives, of people of advanced age and/or impaired health status. However, the SAB Council in its review of the June 2001 draft blueprint recommended that EPA consider reporting results in terms of implied cost-effectiveness using QALYs or value of statistical life year (VSLY). Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint, including the plan to present these results in a less-prominent manner than the benefit-cost-based Primary results (e.g., in a main report sidebar text box or an appendix)? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?

Chapter 9: Uncertainty Analysis

25. Does the Council support the plans described in chapter 9 for estimating and reporting uncertainty associated with the benefit and cost estimates developed for this study? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

26. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the compliance cost estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in cost estimates for this analysis which the Council recommends?

27. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the emissions and air quality modeling estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in emissions and/or air quality concentration estimates for this analysis which the Council recommends?

28. Does the Council support the plans described in chapter 9 for the expert elicitation pilot project to develop a probability-based PM2.5 C-R function for premature mortality, including in particular the elicitation process design? If the Council does not support the expert elicitation pilot project, or any particular aspect of its design, are there alternative approaches the Council recommends for estimating PM-related mortality benefits for this analysis, including in particular a probabilistic distribution for the C-R function to reflect uncertainty in the overall C-R function and/or its components?

29. EPA plans to develop estimates of an independent mortality effect associated with ozone, as described in chapter 9. Does the Council support the use of the most recent literature on the relationship between short-term ozone exposure and daily death rates, specifically that portion of the literature describing models which control for potential confounding by PM2.5? Does the Council agree with the use of that literature as the basis for deriving quantified estimates of an independent mortality impact associated with ozone, especially in scenarios where short-term PM2.5 mortality estimates are used as the basis for quantifying PM mortality related benefits? Does the Council support the plans described in chapter 9 for the pilot project to use this literature to develop estimates of the ozone-related premature mortality C-R function using the three alternative meta-analytic approaches? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying ozone-related premature mortality which the Council recommends?

30. EPA plans to apply the Kochi et al (2002) meta-analysis to derive an initial value for VSL, as described in Appendix H (a separate charge question pertaining to this element of EPA's VSL plan is presented below). In addition, EPA plans to conduct a follow-on meta-regression analysis of the existing VSL literature to provide insight into the systematic impacts of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL. Does the Council support the plans described in chapter 9 for conducting this meta-regression analysis? If the Council does not support this analysis or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the impact of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL?

31. Does the Council support the plans described in chapter 9 for, if necessary upon review and evaluation of the VSL meta-regression, conducting a formal expert elicitation analysis to develop probabilistic representations of the distribution of the value of a statistical life, with the potential for separate distributions developed for individual age groups, and considering potentially influential variables, such as risk characteristics and health status, which may not be completely

captured in the meta-regression? If the Council does not support this expert elicitation project, or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the influence of population or risk characteristics on the VSL estimates to be used in characterizing uncertainty for this study?

Chapter 10: Data Quality and Intermediate Data Products

32. Does the Council support the plans described in chapter 10 for evaluating the quality of data inputs and analytical outputs associated with this study, including the planned publication of intermediate data products and comparison of intermediate and final results with other data or estimates? If the Council does not support these plans, are there alternative approaches, intermediate data products, data or model comparisons, or other data quality criteria the Council recommends?

Chapter 11: Results Aggregation and Reporting

33. Does the Council support the plans described in Chapter 11 for the aggregation and presentation of analytical results from this study? If the Council does not support these plans, are there alternative approaches, aggregation methods, results presentation techniques, or other tools the Council recommends?

Appendix D: Stratospheric Ozone Analysis

34. Does the Council support the plans describe in Appendix D for updating the estimated costs and benefits of Title VI programs? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

Appendix E: Air Toxics Case Study

35. Does the Council support the plans described in Appendix E for the benzene case study, including the planned specific data, models, and methods, and the ways in which these elements have been integrated? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

36. A cessation lag for benzene-induced leukemia is difficult to estimate and model precisely due to data limitations, and EPA plans to incorporate a five-year cessation lag as an approximation based on available data on the latency period of leukemia and on the exposure lags used in risk models for the Pliofilm cohort (Crump, 1994 and Silver et al., 2002). Does the SAB support adoption of this assumed cessation lag? If the Council does not support the assumed five-year cessation lag, are there alternative lag structures or approaches the Council recommends?

Appendix H: Meta-analysis of VSL

37. Does the Council support the plans described in the analytical blueprint to apply the Kochi et al (2002) meta-analysis to derive an estimate for the value of avoided premature mortality attributable to air pollution? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 8, 2003

Dr. Vanessa Vu, Staff Director
Office of the Science Advisory Board
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

OFFICE OF
AIR AND RADIATION

Dear Dr. Vu:

The purpose of this letter is to transmit to the SAB Council (1) a set of revised pages for the section 812 study analytical blueprint and (2) revised charge questions for the Council to consider in its review of the blueprint.

I also want to take this opportunity to apologize to the members of the Council for the delay in their scheduled review of the blueprint and the charge questions. I recognize that many of them had devoted substantial time in reviewing the May 12 version of the blueprint and charge questions and that it was inconvenient, to say the least, that we asked the Council to suspend their review so that we could make revisions to both documents. I believe, however, that the changes we have made to the blueprint and charge questions will result in an improved analysis.

As you know, many EPA offices – not just the Office of Air And Radiation – look to the 812 analysis to guide their benefit-cost analysis. The Council's review and comments are highly relevant to a number of important cross-Agency issues, including probability analysis, VSL issues, use of life years as a metric for benefits or cost-effectiveness, treatment of latency, cessation lags, ecosystem benefit measurement issues, and problems with using avoided costs as a measure of benefits. Before proceeding with the Council's review of these issues in the context of the 812 process, we wanted to be sure that we had fully discussed these issues with the other EPA offices that have an interest in them.

In the past, EPA did not necessarily develop a detailed blueprint. I think our current blueprint represents a big step forward – especially in light of the additional changes we have made in response to comments from other EPA offices – and I am very pleased that the Council will help guide us through the Second Prospective Analysis from the initial planning stage.

Please note that we have tried to format the attached materials in a way that will minimize the disruption caused by our postponement of the initial review. The individual revised blueprint pages attached to this letter are intended to replace the similarly numbered pages in the original May 12 version of the blueprint. Significant changes relative to the May 12 original blueprint are indicated by blue text. A revised set of charge questions is also attached. In addition, to clarify which charge questions have been modified or renumbered, a redline-strikeout version indicating additions and deletions relative to the May 12 original is attached. Please note that we are still working on Chapter 8 of the related to economic valuation. We will send you the changed pages for this chapter within two weeks.

On behalf of the Agency, I want to thank the Council members for their willingness to review and respond to the blueprint and charge questions. We place a high value on the advice and assistance provided by the Council, and we very much look forward to your input as we complete the planning phase of this new analysis and begin study implementation.

Sincerely,

Jeffrey R. Holmstead
Assistant Administrator

24 Attachments

SAB Review Charge Questions
July 3, 2003 - REVISED

This document conveys a set of specific charge questions which EPA respectfully requests that the SAB Council consider during its review of the draft analytical blueprint for the upcoming section 812 benefit-cost study of the Clean Air Act. The charge questions are organized by blueprint chapter or appendix. The first question posed for each chapter or appendix is intended to serve as a general charge question consistent with the statutory criteria for Council review of the section 812 studies. Additional, more detailed charge questions are also conveyed for most chapters and appendices.

These supplemental charge questions reflect EPA's desire to obtain specific and detailed advice from the Council on particular analytical issues.

Chapter 1: Project Goals and Analytical Sequence

1. Does the Council support the study goals, general analytical framework, disaggregation plan, analytical sequence, and general analytical refinements defined in chapter 1? If there are particular elements of these plans which the Council does not support, are there alternatives the Council recommends?

Chapter 2: Scenario Development

2. Does the Council support the choices for analytical scenarios defined in chapter 2? Are there alternative or additional scenarios the Council recommends EPA consider for inclusion in the analysis?

3. Does the Council support the alternative compliance pathway estimation and comparison methodology described in chapter 2, including the specification of alternative compliance pathways which may not reflect precisely constant emissions or air quality outcomes between scenarios due (primarily) to the non-continuous nature and interaction effects of emission control options?

Chapter 3: Emissions Estimation

4. Does the Council support the plans for estimating, evaluating, and reporting emissions changes as defined in chapter 3? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

5. Chapter 3 of the analytical plan describes several alternative approaches considered by EPA for estimating non-EGU emissions growth rates. These options reflect different relative emphasis between two conflicting analytical objectives: (1) extensive refinement of the geographically differentiated, source-specific economic activity growth estimates

embedded in EGAS 4.0, and (2) maintaining the current project schedule and budget. EPA plans to use "approach #4", a compromise option which targets the most important source categories for potential refinement. Does the Council support the initial plan to use "approach #4"? If the Council does not support the use of approach #4, are there other approaches –including either the approaches described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

6. Some state-supplied emissions data incorporated in the 1999 National Emissions Inventory (NEI) –the core emissions inventory for this analysis– incorporate different emissions factors from those used in MOBILE6, the mobile source emissions model EPA plans to use for estimating emissions changes between scenarios. Of particular importance, some of the emissions factors embedded in California's EMFAC model may be significantly different from factors used in MOBILE6. EPA considered three options for estimating emissions changes in California, which are described in chapter 3. EPA plans to implement option #3 based on the belief that the emission factors embedded by California in its EMFAC model may be more accurate for their particular state than the factors incorporated in MOBILE6. Does the Council support the plan to implement option #3? If the Council does not support the adoption of option #3, are there other options –including either the options described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

Chapter 4: Cost Estimates

7. Does the Council support the plans for estimating, evaluating, and reporting compliance costs described in chapter 4? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

8. EPA seeks advice from the Council concerning the choice of Computable General Equilibrium (CGE) model which EPA intends to use as a post-processor to gauge the general equilibrium effects of the various control scenarios. In the first 812 study –the retrospective– EPA used the Jorgenson/Wilcoxen model to gauge the general equilibrium effects of returning to the economy the reported compliance expenditures which formed the basis of the retrospective study direct cost estimates. This model has since been refined in many ways, and EPA considers both the Jorgenson/Wilcoxen/Ho and AMIGA to be acceptable tools. Although a final decision on model choice can be deferred until later in the analysis, EPA has tentative plans to use the AMIGA model because of its greater sectoral disaggregation, better industrial sector matching with CAA-affected industries, richer representation of relevant production and consumption technologies, and better model validation opportunities due to its use of open code. However, AMIGA is limited given its inability to deal with dynamics over time. Does the Council support the current, tentative plan to use the AMIGA model for this purpose? If not, are there alternative model choices or selection criteria the Council recommends?

9. In the two previous 812 studies, the primary cost estimates reflected use of a 5 percent real discount rate, which an earlier Council endorsed as a reasonable compromise between a 3 percent real rate considered by EPA to be an appropriate estimate of the consumption rate of interest or rate of social time preference and a 7 percent rate, OMB's estimate of the opportunity cost of capital. Limited sensitivity testing was also conducted in the previous 812 studies by substituting 3 and 7 percent rates to annualize the benefit and cost streams. EPA's new Economics Guidelines (peer-reviewed by the SAB EEAC) call for using both a 3 and a 7 percent rate. A recent draft of new OMB economic guidelines suggests providing results based on both 3 and 7 percent discount rates, while also acknowledging the need for further efforts to refine analytical policies for discounting methods and rates. EPA plans on following both sets of Guideline documents by using both 3 and 7 percent in our core analyses. It is true that this will require presentation of two sets of results – one based on each rate. This may not be necessary given the expected insensitivity of the overall results to the discount rate assumption. Does the Council support this approach? If not, are there alternative rates, discounting concepts, methods, or results presentation approaches the Council recommends?

Chapter 5: Air Quality Modeling

10. Does the Council support the plans described in chapter 5 for estimating, evaluating, and reporting air quality changes associated with the analytical scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

Chapter 6: Human Health Effects Estimation

11. Does the Council support the plans described in chapter 6 for estimating, evaluating, and reporting changes in health effect outcomes between scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

12. EPA seeks advice from the Council regarding the technical and scientific merits of incorporating several new or revised endpoint treatments in the current analysis. These health effect endpoints include:

    a. Premature mortality from particulate matter in adults 30 and over, PM (Krewski et al., 2000);

    b. A PM premature mortality supplemental calculation for adults 30 and over using the Pope 2002 ACS follow-up study with regional controls;

    c. Hospital admissions for all cardiovascular causes in adults 20-64, PM (Moolgavkar et al., 2000);

d. ER visits for asthma in children 0-18, PM (Norris et al., 1999);

e. Non-fatal heart attacks, adults over 30, PM (Peters et al., 2001);

f. School loss days, Ozone (Gilliland et al., 2001; Chen et al., 2000);

g. Hospital admissions for all respiratory causes in children under 2, Ozone (Burnett et al., 2001); and,

h. Revised sources for concentration-response functions for hospital admission for pneumonia, COPD, and total cardiovascular: Samet et al., 2000 (a PM10 study), to Lippmann et al., 2000 and Moolgavkar, 2000 (PM2.5 studies).

13. EPA seeks advice from the Council regarding the merits of applying updated data for baseline health effect incidences, prevalence rates, and other population characteristics as described in chapter 6. These updated incidence/prevalence data include:

a. Updated county-level mortality rates (all-cause, non-accidental, cardiopulmonary, lung cancer, COPD) from 1994-1996 to 1996-1998 using the CDC Wonder database;

b. Updated hospitalization rates from 1994 to 1999 and switched from national rates to regional rates using 1999 National Hospital Discharge Survey results;

c. Developed regional emergency room visit rates using results of the 2000 National Hospital Ambulatory Medical Care Survey;

d. Updated prevalence of asthma and chronic bronchitis to 1999 using results of the National Health Interview Survey (HIS), as reported by the American Lung Association (ALA), 2002;

e. Developed non-fatal heart attack incidence rates based on National Hospital Discharge Survey results;

f. Updated the national acute bronchitis incidence rate using HIS data as reported in ALA, 2002, Table 11;

g. Updated the work loss days rate using the 1996 HIS data, as reported in Adams, et al. 1999, Table 41;

h. Developed school absence rates using data from the National Center for Education Statistics and the 1996 HIS, as reported in Adams, et al., 1999, Table 46.

1. Developed baseline incidence rates for respiratory symptoms in asthmatics, based on epidemiological studies (Ostro et al. 2001; Vedal et al. 1998; Yu et al; 2000; McConnell et al., 1999; Pope et al., 1991).

14. EPA plans to initiate an expert elicitation process to develop a probability-based method for estimating changes in incidence of PM-related premature mortality. Plans for this expert elicitation are described in chapter 9 of this blueprint, and a separate charge question below requests advice from the Council pertaining to the merits of the design of this expert elicitation. EPA recognizes, however, the possibility that this expert elicitation process may not be fully successful and/or may not be completed in time to support the current 812 analysis. Therefore, in order to facilitate effective planning and execution of the early analytical steps which provide inputs to the concentration-response calculations, EPA seeks advice from the Council regarding the scientific merits of alternative methods for estimating the incidences of PM-related premature mortality, including advice pertaining to the most scientifically defensible choices for the following specific factors:

    a. Use of cohort mortality studies, daily mortality studies, or some combination of the two types of studies

    b. Selection of specific studies for estimating long-term and/or short-term mortality effects

    c. Methods for addressing –either quantitatively or qualitatively– uncertain factors associated with the relevant concentration-response function(s), including

        i. Shape of the PM mortality C-R function (e.g., existence of a threshold),
        ii. PM causality,
        iii. PM component relative toxicity, and
        iv. PM mortality effect cessation lag structure
        v. Cause of death and underlying health conditions for individuals dying prematurely due to chronic and/or short term exposures to particulate matter
        vi. The use of ambient measures of exposure for estimating chronic health effects, given recent research reviewed in the NAS (2002) report that questions the implications of using ambient measures in cohort studies

15. EPA estimates of benefit from particulate control may underestimate the impact of nonfatal cardiopulmonary events on premature mortality and life expectancy. For the base analyses, which rely on cohort evidence, the limited follow-up periods for the cohorts may not fully capture the impacts of nonfatal cardiovascular events on premature mortality later in life. For the alternative analyses –including cost-effectiveness analyses– which rely more on acute studies and life-expectancy loss, the years of life are estimated only for fatal events. Yet nonfatal events such as myocardial infarction reduce a person's life expectancy by a substantial percentage.

    a. Do you agree that EPA, in the 812 analyses, should adjust benefit estimates to account for the mortality effects of non-fatal cardiovascular and respiratory events?

b. What medical studies and mathematical models of disease might be useful to review or use if EPA moves in this direction?

c. When the nonfatal events are valued in economic terms, should EPA assume that the published unit values for morbidity already account for the life-expectancy loss or should an explicit effort be made to monetize the resulting longevity losses?

16. In recent EPA rulemakings, EPA's "base estimate" of benefit from PM control has been based on cohort epidemiological studies that characterize the chronic effects of pollution exposure on premature death as well as capturing a fraction of acute premature mortality effects. If these chronic effects occur only after repeated, long-term exposures, there could be a substantial latency period and associated cessation lag. As such, a proper benefits analysis must consider any time delay between reductions in exposure and reductions in mortality rates. For the acute effects, such as those considered in EPA's alternative benefit analyses, the delays between elevated exposure and death are short (less than two months), and thus time-preference adjustments are not necessary.

a. In the previous 812 analysis and in recent rulemakings, EPA assumed a weighted 5-year time course of benefits in which 25% of the PM-related mortality benefits were assumed to occur in the first and second year, and 16.7% were assumed to occur in each of the remaining 3 years. Although this procedure was endorsed by SAB, the recent NAS report (2002) found "little justification" for a 5-year time course and recommended that a range of assumptions be made with associated probabilities for their plausibility. Do you agree with the NAS report that EPA should no longer use the deterministic, 5-year time course?

b. One alternative EPA is considering is to use a range of lag structures from 0 to 20-30 years, with the latter mentioned by NAS in reference to the Nyberg et al PM lung cancer study, with 10 or 15 years selected as the mid-point value until more definitive information becomes available. If this simple approach is used, should it be applied to the entire mortality association characterized in the cohort studies, or only to the difference between the larger mortality effect characterized in the cohort studies and the somewhat smaller effect found in the time series studies of acute exposure? Should judgmental probabilities be applied to different lags, as suggested by NAS?

c. Another option under consideration is to construct a 3-parameter Weibull probability distribution for the population mean duration of the PM mortality cessation lag. The Weibull distribution is commonly used to represent probabilities based on expert judgment, with the 3-parameter version allowing the shaping of the probability density function to match expected low, most likely, and expected high values. EPA is still considering appropriate values for the low, most likely, and expected high values –and therefore for the Weibull shape and location parameters– and EPA is interested in any advice the Council wishes to provide pertaining to the merits of this approach and/or reasonable values for the probability distribution.

17. In support of Clear Skies and several recent rule makings the Agency has presented an Alternative Estimate of benefits as well as the Base Estimate. EPA developed the Alternative Estimate as an interim approach until the Agency completes a formal probabilistic analysis of benefits. NAS (2002) reinforced the need for a probabilistic analysis. The Alternative Estimate is not intended as a substitute method and needs to be considered in conjunction with the Base Estimate. Presentation of Base and Alternative estimates in the 812 Report may not be necessary if the probability analysis planned for the 812 Report is successful. While the Base Estimate assumes that acute and chronic mortality effects are causally related to pollution exposure, the Alternative Estimate assumes only acute effects occur or that any chronic effects are smaller in size than assumed in the Base Estimate. The Council's advice is sought on the following matters:

    a. It has been noted by some particle scientists that the size of estimates based on time series studies that incorporate a distributed lag model, accounting for effects of 30 to 60 days after elevated exposure, may be similar in size to some interpretations of the results from the cohort studies. Does the Council agree that it is a reasonable alternative to use an estimate of the concentration-response function consistent with this view? If the Council agrees with the assumption, can it suggest an improved approach for use in an Alternative Estimate? The agency also seeks advice on appropriate bounds for a sensitivity analysis of the mortality estimate to be used in support of the Alternative Estimate.

    b. An assumption that a specific proportion of the PM-related premature mortality incidences are incurred by people with pre-existing Chronic Obstructive Pulmonary Disease (COPD) and that these incidences are associated with a loss of six months of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

    c. An assumption that the non-COPD incidences of PM-related premature mortality are associated with a loss of five years of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

    d. Additional quantified and/or monetized effects are those presented as sensitivity analyses to the primary estimates or in addition to the primary estimates, but not included in the primary estimate of total monetized benefits. While no causal mechanism has been identified for chronic asthma and ozone exposure, there is suggestive epidemiological evidence.

i. Two studies suggest a statistical association between ozone and new onset asthma for two specific groups: children who spend a lot of time exercising outdoors and non-smoking men. We seek SAB comment on our approach to quantifying new onset asthma in the sensitivity analyses.

ii. Premature mortality associated with ozone is not currently separately included in the primary analysis because the epidemiological evidence is not consistent. We seek SAB comment on our approach to quantifying ozone mortality in the sensitivity analyses.

iii. Does the Council agree that there is enough data to support a separate set of health impacts assessment for asthmatics? If so, does the approach proposed by the Agency address the uncertainty in the literature?

Chapter 7: Ecological Effects

18. Does the Council support the plans described in chapter 7 for (a) qualitative characterization of the ecological effects of Clean Air Act-related air pollutants, (b) an expanded literature review, and (c) a quantitative, ecosystem-level case study of ecological service flow benefits? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

19. Initial plans described in chapter 7 reflect a preliminary EPA decision to base the ecological benefits case study on Waquoit Bay in Massachusetts. Does the Council support these plans? If the Council does not support these specific plans, are there alternative case study designs the Council recommends?

20. Does the Council support the plan for a feasibility analysis for a hedonic property study for valuing the effects of nitrogen deposition/eutrophication effects in the Chesapeake Bay region, with the idea that these results might complement the Waquoit Bay analysis?

Chapter 8: Economic Valuation

21. Does the Council support the plans described in chapter 8 for economic valuation of changes in outcomes between the scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

22. EPA's current analytic blueprint calls for an expert-judgment project on VSL determination that would produce a probability distribution over the range of possible VSL values for use in the 812 project. EPA is not sure how much priority to give to this project. A much simpler alternative would be for EPA to specify a plausible range of VSL values. One option would be to use a range bounded by $1 million (based roughly on the lower bound of the interquartile range from the Mrozek-Taylor meta-analysis) and $10 million (based roughly on the upper bound of the interquartile range of the Viscusi-

Aldy meta-analysis. This range would match that reflected in EPA's sensitivity analysis of the alternative benefit estimate for the off-road diesel rulemaking. The range would then be characterized using a normal, half-cosine, uniform or triangular distribution over that range of VSL values. EPA would then ask this Committee to review this distribution. This approach could be done relatively quickly, based on the reviews and meta-analyses commissioned to date, and would allow a formal probability analysis to proceed, without suggesting that the Agency is trying to bring more precision to this issue than is warranted by the available science.

23. Pursuant to SAB Council advice from the review of the first draft analytical blueprint, EPA reviewed a number of meta-analyses –either completed or underway– developed to provide estimates for the value of statistical life (VSL) to be applied in the current study. EPA plans to consult with the Council (and coordinate this consultation with the EEAC) on how best to incorporate information from the Kochi et al (2002) meta-analysis, other published meta-analyses [Mrozek and Taylor and Viscusi and Aldy], and recent published research to develop estimates of VSL for use in this study. In addition, EPA plans to implement two particular adjustments to the core VSL values: discounting of lagged effects and longitudinal adjustment to reflect changes in aggregate income. Does the Council support these plans, including the specific plans for the adjustments described in chapter 8? If the Council does not support these plans, are there alternative data or methods the Council recommends?

24. For the 812 Report, EPA has decided to perform a cost-effectiveness analysis of the Clean Air Act provisions using quality-adjusted life years as the measure of effectiveness. This is the standard approach used in medicine and public health and this type of analysis has previously been recommended by the SAB. Moreover, the recent NAS Report (2002) on benefits analysis discussed how this method could be applied to the health gains from air pollution control.

    a. Do you agree that QALYs are the most appropriate measure of effectiveness for this type of analysis? Would you suggest any alternative measures to replace or supplement the QALY measure? (This question relates to effectiveness measures, not monetary benefit measures as used in benefit-cost analysis).

    b. OMB has suggested that EPA plan a workshop with clinicians, social scientists, decision analysts and economists to examine how the specific diseases and health effects in the 812 Report should be handled with respect to longevity impact and health-related preference. Participants would have knowledge of the relevant clinical conditions, the related health preference studies, and the stated-preference literature in economics. The recent RFF conference has laid the groundwork for this type of workshop. Is there a superior approach to making sure that the CEA-QALY project is executed in a technically competent fashion and that the details of the work receive in-depth technical input in addition to the broad oversight provided by this Committee?

c. Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?

25. EPA plans to use updated unit values for a number of morbidity effects, as described in chapter 8. Of particular note, EPA plans to rely on a study by Dickie and Ulery (2002) to provide heretofore unavailable estimates of parental willingness to pay to avoid respiratory symptoms in their children. This study is not yet published and has limitations concerning response rate and sample representativeness; however, EPA expects the study to be published prior to completion of the economic valuation phase of this analysis. Does the Council support the application of unit values from this study, contingent on its acceptance for publication in a peer-reviewed journal? If the Council does not support reliance on this study, are there other data or methods for valuation of respiratory symptoms in children which the Council recommends?

Chapter 9: Uncertainty Analysis

26. Does the Council support the plans described in chapter 9 for estimating and reporting uncertainty associated with the benefit and cost estimates developed for this study? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

27. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the compliance cost estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in cost estimates for this analysis which the Council recommends?

28. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the emissions and air quality modeling estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in emissions and/or air quality concentration estimates for this analysis which the Council recommends?

29. Does the Council support the plans described in chapter 9 for the expert elicitation pilot project to develop a probability-based PM2.5 C-R function for premature mortality, including in particular the elicitation process design? If the Council does not support the expert elicitation pilot project, or any particular aspect of its design, are there alternative approaches the Council recommends for estimating PM-related mortality benefits for this analysis, including in particular a probabilistic distribution for the C-R function to reflect uncertainty in the overall C-R function and/or its components?

30. EPA plans to develop estimates of an independent mortality effect associated with ozone, as described in chapter 9. Does the Council support the use of the most recent literature on the relationship between short-term ozone exposure and daily death rates, specifically that portion of the literature describing models which control for potential confounding by PM2.5? Does the Council agree with the use of that literature as the basis for deriving quantified estimates of an independent mortality impact associated with ozone, especially in scenarios where short-term PM2.5 mortality estimates are used as the basis for quantifying PM mortality related benefits? Does the Council support the plans described in chapter 9 for the pilot project to use this literature to develop estimates of the ozone-related premature mortality C-R function using the three alternative meta-analytic approaches? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying ozone-related premature mortality which the Council recommends?

31. EPA plans to work with the Council and the EEAC to develop revised guidance on appropriate VSL measures. We hope to include the Kochi et al (2002) meta-analysis, other recent meta-analysis, recent publications, and the 3 literature reviews sponsored by EPA.(a separate charge question pertaining to this element of EPA's VSL plan is presented below). In addition, EPA plans to conduct a follow-on meta-regression analysis of the existing VSL literature to provide insight into the systematic impacts of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL. Does the Council support the plans described in chapter 9 for conducting this meta-regression analysis? If the Council does not support this analysis or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the impact of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL?

Chapter 10: Data Quality and Intermediate Data Products

32. Does the Council support the plans described in chapter 10 for evaluating the quality of data inputs and analytical outputs associated with this study, including the planned publication of intermediate data products and comparison of intermediate and final results with other data or estimates? If the Council does not support these plans, are there alternative approaches, intermediate data products, data or model comparisons, or other data quality criteria the Council recommends? Please consider EPA's Information Quality Guidelines in this regard.

Chapter 11: Results Aggregation and Reporting

33. Does the Council support the plans described in Chapter 11 for the aggregation and presentation of analytical results from this study? If the Council does not support these

plans, are there alternative approaches, aggregation methods, results presentation techniques, or other tools the Council recommends?

Appendix D: Stratospheric Ozone Analysis

34. Does the Council support the plans describe in Appendix D for updating the estimated costs and benefits of Title VI programs? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

Appendix E: Air Toxics Case Study

35. Does the Council support the plans described in Appendix E for the benzene case study, including the planned specific data, models, and methods, and the ways in which these elements have been integrated? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

36. A cessation lag for benzene-induced leukemia is difficult to estimate and model precisely due to data limitations, and EPA plans to incorporate a five-year cessation lag as an approximation based on available data on the latency period of leukemia and on the exposure lags used in risk models for the Pliofilm cohort (Crump, 1994 and Silver et al., 2002). Does the SAB support adoption of this assumed cessation lag? If the Council does not support the assumed five-year cessation lag, are there alternative lag structures or approaches the Council recommends?

Appendix H: Meta-analysis of VSL

37. Does the Council support including the Kochi et al. (2002) meta-analysis as part of a the larger data base of studies to derive an estimate for the value of avoided premature mortality attributable to air pollution? Are there additional data, models, or studies the Council recommends? Does the SAB think that EPA should include Kochi et al. 2003 if not accepted for publication in a peer reviewed journal by the time the final 812 report is completed?

SAB Review Charge Questions
July 2, 2003 - REVISED

This document conveys a set of specific charge questions which EPA respectfully requests that the SAB Council consider during its review of the draft analytical blueprint for the upcoming section 812 benefit-cost study of the Clean Air Act. The charge questions are organized by blueprint chapter or appendix. The first question posed for each chapter or appendix is intended to serve as a general charge question consistent with the statutory criteria for Council review of the section 812 studies.[1] Additional, more detailed charge questions are also conveyed for most chapters and appendices.

These supplemental charge questions reflect EPA's desire to obtain specific and detailed advice from the Council on particular analytical issues.

Chapter 1: Project Goals and Analytical Sequence

1. Does the Council support the study goals, general analytical framework, disaggregation plan, analytical sequence, and general analytical refinements defined in chapter 1? If there are particular elements of these plans which the Council does not support, are there alternatives the Council recommends?

Chapter 2: Scenario Development

2. Does the Council support the choices for analytical scenarios defined in chapter 2? Are there alternative or additional scenarios the Council recommends EPA consider for inclusion in the analysis?

3. Does the Council support the alternative compliance pathway estimation and comparison methodology described in chapter 2, including the specification of alternative compliance pathways which may not reflect precisely constant emissions or air quality outcomes between scenarios due (primarily) to the non-continuous nature and interaction effects of emission control options?

[1] ~~(g) The Council shall–~~
~~(1) review the data to be used for any analysis required under this section and make recommendations to the Administrator on the use of such data;~~
~~(2) review the methodology used to analyze such data and make recommendations to the Administrator on the use of such methodology; and~~
~~(3) prior to the issuance of a report required under subsection (d) or (e), review the findings of such report, and make recommendations to the Administrator concerning the validity and utility of such findings. [CAA §312(g)(1)-(3)]~~

Chapter 3: Emissions Estimation

4. Does the Council support the plans for estimating, evaluating, and reporting emissions changes as defined in chapter 3? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

5. Chapter 3 of the analytical plan describes several alternative approaches considered by EPA for estimating non-EGU emissions growth rates. These options reflect different relative emphasis between two conflicting analytical objectives: (1) extensive refinement of the geographically differentiated, source-specific economic activity growth estimates embedded in EGAS 4.0, and (2) maintaining the current project schedule and budget. EPA plans to use "approach #4", a compromise option which targets the most important source categories for potential refinement. Does the Council support the initial plan to use "approach #4"? If the Council does not support the use of approach #4, are there other approaches –including either the approaches described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

6. Some state-supplied emissions data incorporated in the 1999 National Emissions Inventory (NEI) –the core emissions inventory for this analysis– incorporate different emissions factors from those used in MOBILE6, the mobile source emissions model EPA plans to use for estimating emissions changes between scenarios. Of particular importance, some of the emissions factors embedded in California's EMFAC model may be significantly different from factors used in MOBILE6. EPA considered three options for estimating emissions changes in California, which are described in chapter 3. EPA plans to implement option #3 based on the belief that the emission factors embedded by California in its EMFAC model may be more accurate for their particular state than the factors incorporated in MOBILE6. Does the Council support the plan to implement option #3? If the Council does not support the adoption of option #3, are there other options –including either the options described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

Chapter 4: Cost Estimates

7. Does the Council support the plans for estimating, evaluating, and reporting compliance costs described in chapter 4? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

8. EPA seeks advice from the Council concerning the choice of Computable General Equilibrium (CGE) model which EPA intends to use as a post-processor to gauge the general equilibrium effects of the various control scenarios. In the first 812 study –the retrospective– EPA used the Jorgenson/Wilcoxen model to gauge the general equilibrium effects of returning to the economy the reported compliance expenditures which formed the basis of the retrospective study direct cost estimates. This model has since been

refined in many ways, and EPA considers both the Jorgenson/Wilcoxen/Ho and AMIGA to be acceptable tools. Although a final decision on model choice can be deferred until later in the analysis, EPA has tentative plans to use the AMIGA model because of its greater sectoral disaggregation, better industrial sector matching with CAA-affected industries, richer representation of relevant production and consumption technologies, and better model validation opportunities due to its use of open code. However, AMIGA is limited given its inability to deal with dynamics over time. Does the Council support the current, tentative plan to use the AMIGA model for this purpose? If not, are there alternative model choices or selection criteria the Council recommends?

9. ~~In the two previous 812 studies, the primary cost estimates reflected use of a 5 percent real discount rate, which an earlier Council endorsed as a reasonable compromise between a 3 percent real rate considered by EPA to be most consistent with prevailing literature and a 7 percent rate based on the 1992 update of OMB's Circular A-94. The EPA-preferred 3 percent rate was, and is, designed to be consistent with a consumption rate of interest discounting concept, while the OMB-preferred 7 percent rate was, and is, intended to reflect the opportunity cost of private capital investment. Limited sensitivity testing was also conducted in the previous 812 studies by substituting –where possible– 3 and 7 percent rates to annualize the benefit and cost streams. EPA's new Economics Guidelines (peer-reviewed by the SAB EEAC) call for using a 2-3 percent rate consistent with the consumption rate of interest for primary analysis while acknowledging the need to also provide results based on a 7 percent rate as required by OMB Circular A-94. A recent draft of new OMB economic guidelines suggests providing results based on both 3 and 7 percent discount rates, while also acknowledging the need for further efforts to refine analytical policies for discounting methods and rates. EPA is concerned that presentation of multiple sets of "primary" results may breed unjustifiable confusion, particularly given the expected insensitivity of the overall results to the discount rate assumption. Therefore, EPA proposes to base the "primary" estimates on a 3 percent rate consistent with both prevailing peer-reviewed EPA Economic Guidelines, and to present these estimates as the principal results of the analysis. The 812 analysis would also conduct and present sensitivity tests using the OMB-prescribed 7 percent rate. Does the Council support this approach? If not, are there alternative rates, discounting concepts, methods, or results presentation approaches the Council recommends?~~

In the two previous 812 studies, the primary cost estimates reflected use of a 5 percent real discount rate, which an earlier Council endorsed as a reasonable compromise between a 3 percent real rate considered by EPA to be an appropriate estimate of the consumption rate of interest or rate of social time preference and a 7 percent rate, OMB's estimate of the opportunity cost of capital. Limited sensitivity testing was also conducted in the previous 812 studies by substituting 3 and 7 percent rates to annualize the benefit and cost streams. EPA's new Economics Guidelines (peer-reviewed by the SAB EEAC) call for using both a 3 and a 7 percent rate. A recent draft of new OMB economic guidelines suggests providing results based on both 3 and 7 percent discount rates, while also acknowledging the need for further efforts to refine analytical policies for discounting methods and rates. EPA plans on following both sets of Guideline documents by using both 3 and 7 percent in our core analyses. It is true that this will

require presentation of two sets of results – one based on each rate. This may not be necessary given the expected insensitivity of the overall results to the discount rate assumption. Does the Council support this approach? If not, are there alternative rates, discounting concepts, methods, or results presentation approaches the Council recommends?

Chapter 5: Air Quality Modeling

10. Does the Council support the plans described in chapter 5 for estimating, evaluating, and reporting air quality changes associated with the analytical scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

Chapter 6: Human Health Effects Estimation

11. Does the Council support the plans described in chapter 6 for estimating, evaluating, and reporting changes in health effect outcomes between scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

12. EPA seeks advice from the Council regarding the technical and scientific merits of incorporating several new or revised endpoint treatments in the current analysis. These health effect endpoints include:

    a. Premature mortality from particulate matter in adults 30 and over, PM (Krewski et al., 2000);

    b. A PM premature mortality supplemental calculation for adults 30 and over using the Pope 2002 ACS follow-up study with regional controls;

    c. Hospital admissions for all cardiovascular causes in adults 20-64, PM (Moolgavkar et al., 2000);

    d. ER visits for asthma in children 0-18, PM (Norris et al., 1999);

    e. Non-fatal heart attacks, adults over 30, PM (Peters et al., 2001);

    f. School loss days, Ozone (Gilliland et al., 2001; Chen et al., 2000);

    g. Hospital admissions for all respiratory causes in children under 2, Ozone (Burnett et al., 2001); and,

    h. Revised sources for concentration-response functions for hospital admission for pneumonia, COPD, and total cardiovascular: Samet et al., 2000 (a PM10 study),

to Lippmann et al., 2000 and Moolgavkar, 2000 (PM2.5 studies).

13. EPA seeks advice from the Council regarding the merits of applying updated data for baseline health effect incidences, prevalence rates, and other population characteristics as described in chapter 6. These updated incidence/prevalence data include:

    a. Updated county-level mortality rates (all-cause, non-accidental, cardiopulmonary, lung cancer, COPD) from 1994-1996 to 1996-1998 using the CDC Wonder database;

    b. Updated hospitalization rates from 1994 to 1999 and switched from national rates to regional rates using 1999 National Hospital Discharge Survey results;

    c. Developed regional emergency room visit rates using results of the 2000 National Hospital Ambulatory Medical Care Survey;

    d. Updated prevalence of asthma and chronic bronchitis to 1999 using results of the National Health Interview Survey (HIS), as reported by the American Lung Association (ALA), 2002;

    e. Developed non-fatal heart attack incidence rates based on National Hospital Discharge Survey results;

    f. Updated the national acute bronchitis incidence rate using HIS data as reported in ALA, 2002, Table 11;

    g. Updated the work loss days rate using the 1996 HIS data, as reported in Adams, et al. 1999, Table 41;

    h. Developed school absence rates using data from the National Center for Education Statistics and the 1996 HIS, as reported in Adams, et al., 1999, Table 46.

    1. Developed baseline incidence rates for respiratory symptoms in asthmatics, based on epidemiological studies (Ostro et al. 2001; Vedal et al. 1998; Yu et al; 2000; McConnell et al., 1999; Pope et al., 1991).

14. EPA plans to initiate an expert elicitation process to develop a probability-based method for estimating changes in incidence of PM-related premature mortality. Plans for this expert elicitation are described in chapter 9 of this blueprint, and a separate charge question below requests advice from the Council pertaining to the merits of the design of this expert elicitation. EPA recognizes, however, the possibility that this expert elicitation process may not be fully successful and/or may not be completed in time to support the current 812 analysis. Therefore, in order to facilitate effective planning and

execution of the early analytical steps which provide inputs to the concentration-response calculations, EPA seeks advice from the Council regarding the scientific merits of alternative methods for estimating the incidences of PM-related premature mortality, including advice pertaining to the most scientifically defensible choices for the following specific factors:

a. Use of cohort mortality studies, daily mortality studies, or some combination of the two types of studies

b. Selection of specific studies for estimating long-term and/or short-term mortality effects

c. Methods for addressing –either quantitatively or qualitatively– uncertain factors associated with the relevant concentration-response function(s), including

i. Shape of the PM mortality C-R function (e.g., existence of a threshold);
ii. PM causality,
iii. PM component relative toxicity, and
iv. PM mortality effect cessation lag structure
v. Cause of death and underlying health conditions for individuals dying prematurely due to chronic and/or short term exposures to particulate matter
vi. The use of ambient measures of exposure for estimating chronic health effects, given recent research reviewed in the NAS (2002) report that questions the implications of using ambient measures in cohort studies

15. EPA estimates of benefit from particulate control may underestimate the impact of nonfatal cardiopulmonary events on premature mortality and life expectancy. For the base analyses, which rely on cohort evidence, the limited follow-up periods for the cohorts may not fully capture the impacts of nonfatal cardiovascular events on premature mortality later in life. For the alternative analyses –including cost-effectiveness analyses– which rely more on acute studies and life-expectancy loss, the years of life are estimated only for fatal events. Yet nonfatal events such as myocardial infarction reduce a person's life expectancy by a substantial percentage.

a. Do you agree that EPA, in the 812 analyses, should adjust benefit estimates to account for the mortality effects of non-fatal cardiovascular and respiratory events?

b. What medical studies and mathematical models of disease might be useful to review or use if EPA moves in this direction?

c. When the nonfatal events are valued in economic terms, should EPA assume that the published unit values for morbidity already account for the life-expectancy

loss or should an explicit effort be made to monetize the resulting longevity losses?

16. In recent EPA rulemakings, EPA's "base estimate" of benefit from PM control has been based on cohort epidemiological studies that characterize the chronic effects of pollution exposure on premature death as well as capturing a fraction of acute premature mortality effects. If these chronic effects occur only after repeated, long-term exposures, there could be a substantial latency period and associated cessation lag. As such, a proper benefits analysis must consider any time delay between reductions in exposure and reductions in mortality rates. For the acute effects, such as those considered in EPA's alternative benefit analyses, the delays between elevated exposure and death are short (less than two months), and thus time-preference adjustments are not necessary.

    a. In the previous 812 analysis and in recent rulemakings, EPA assumed a weighted 5-year time course of benefits in which 25% of the PM-related mortality benefits were assumed to occur in the first and second year, and 16.7% were assumed to occur in each of the remaining 3 years. Although this procedure was endorsed by SAB, the recent NAS report (2002) found "little justification" for a 5-year time course and recommended that a range of assumptions be made with associated probabilities for their plausibility. Do you agree with the NAS report that EPA should no longer use the deterministic, 5-year time course?

    b. One alternative EPA is considering is to use a range of lag structures from 0 to 20-30 years, with the latter mentioned by NAS in reference to the Nyberg et al PM lung cancer study, with 10 or 15 years selected as the mid-point value until more definitive information becomes available. If this simple approach is used, should it be applied to the entire mortality association characterized in the cohort studies, or only to the difference between the larger mortality effect characterized in the cohort studies and the somewhat smaller effect found in the time series studies of acute exposure? Should judgmental probabilities be applied to different lags, as suggested by NAS?

    c. Another option under consideration is to construct a 3-parameter Weibull probability distribution for the population mean duration of the PM mortality cessation lag. The Weibull distribution is commonly used to represent probabilities based on expert judgment, with the 3-parameter version allowing the shaping of the probability density function to match expected low, most likely, and expected high values. EPA is still considering appropriate values for the low, most likely, and expected high values –and therefore for the Weibull shape and location parameters– and EPA is interested in any advice the Council wishes to provide pertaining to the merits of this approach and/or reasonable values for the probability distribution.

~~15. In two recent mobile source rulemaking analyses, two recent Title III MACT rulemaking~~

~~analyses, and the benefits analysis for the Clear Skies Initiative, EPA included an "Alternative Estimate" in addition to a "Base Estimate" of total monetized benefits. The estimates included in these five analyses differed in some respects, but in each case they reflected some combination of alternative assumptions regarding key factors in the estimation of PM-related benefits, particularly premature mortality and chronic bronchitis. Because these alternative estimates were motivated in part by the lack of a more fully developed probabilistic methodology able to incorporate the most important analytical uncertainties –and a more extensive probabilistic uncertainty analysis is in the 812 Report may not be necessary if the probability analysis planned for the current analysis= EPA plans not to incorporate an Alternative Estimate similar to those adopted in the five recent EPA analyses. However, if the probability-based uncertainty analysis is not considered sufficiently extended by other federal agencies, there may be significant pressure on EPA to incorporate an Alternative Estimate similar, or identical, to those incorporated in the recent analyses. EPA seeks advice from the Council pertaining to the merits and utility of adding an Alternative Estimate similar to those incorporated in the five recent EPA analyses, either in addition to or in lieu of a probability-based uncertainty analysis. In addition to providing advice on the overall merit of using an Alternative Estimate approach, EPA seeks advice pertaining to the scientific and technical merit of three specific adjustments to EPA Primary Estimate methods incorporated in the recent Alternative Estimates, including:~~

~~a. Exclusive reliance on short-term mortality studies to estimate PM incidence changes (i.e., an assumption of zero effect from chronic exposure)~~

~~b. An assumption that a specific proportion of the PM-related premature mortality incidences are incurred by people with pre-existing Chronic Obstructive Pulmonary Disease (COPD) and that these incidences are associated with a loss of six months of life, regardless of age at death~~

~~c. An assumption that the non-COPD incidences of PM-related premature mortality are associated with a loss of five years of life, regardless of age at death~~

~~d. (Additional components of the Alternative Estimate, including differences in valuation method, are addressed in a separate charge question below.)~~

17. In support of Clear Skies and several recent rule makings the Agency has presented an Alternative Estimate of benefits as well as the Base Estimate. EPA developed the Alternative Estimate as an interim approach until the Agency completes a formal probabilistic analysis of benefits. NAS (2002) reinforced the need for a probabilistic analysis. The Alternative Estimate is not intended as a substitute method and needs to be considered in conjunction with the Base Estimate. Presentation of Base and Alternative estimates in the 812 Report may not be necessary if the probability analysis planned for the 812 Report is successful. While the Base Estimate assumes that acute and chronic mortality effects are causally related to pollution exposure, the Alternative Estimate assumes only acute effects occur or that any chronic effects are smaller in size than assumed in the Base Estimate. The Council's advice is sought on the following matters:

a. It has been noted by some particle scientists that the size of estimates based on time series studies that incorporate a distributed lag model, accounting for effects of 30 to 60 days after elevated exposure, may be similar in size to some interpretations of the results from the cohort studies. Does the Council agree that it is a reasonable alternative to use an estimate of the concentration-response function consistent with this view? If the Council agrees with the assumption, can it suggest an improved approach for use in an Alternative Estimate? The agency also seeks advice on appropriate bounds for a sensitivity analysis of the mortality estimate to be used in support of the Alternative Estimate.

b. An assumption that a specific proportion of the PM-related premature mortality incidences are incurred by people with pre-existing Chronic Obstructive Pulmonary Disease (COPD) and that these incidences are associated with a loss of six months of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

c. An assumption that the non-COPD incidences of PM-related premature mortality are associated with a loss of five years of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

d. Additional quantified and/or monetized effects are those presented as sensitivity analyses to the primary estimates or in addition to the primary estimates, but not included in the primary estimate of total monetized benefits. While no causal mechanism has been identified for chronic asthma and ozone exposure, there is suggestive epidemiological evidence.

   i. Two studies suggest a statistical association between ozone and new onset asthma for two specific groups: children who spend a lot of time exercising outdoors and non-smoking men. We seek SAB comment on our approach to quantifying new onset asthma in the sensitivity analyses.

   ii. Premature mortality associated with ozone is not currently separately included in the primary analysis because the epidemiological evidence is not consistent. We seek SAB comment on our approach to quantifying ozone mortality in the sensitivity analyses.

   iii. Does the Council agree that there is enough data to support a separate set of health impacts assessment for asthmatics? If so, does the approach proposed by the Agency address the uncertainty in the literature?

Chapter 7: Ecological Effects

~~16.~~18. Does the Council support the plans described in chapter 7 for (a) qualitative characterization of the ecological effects of Clean Air Act-related air pollutants, (b) an expanded literature review, and (c) a quantitative, ecosystem-level case study of ecological service flow benefits? ~~-~~If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

~~17.~~19. Initial plans described in chapter 7 reflect a preliminary EPA decision to base the ecological benefits case study on Waquoit Bay in Massachusetts. ~~-~~Does the Council support these plans? If the Council does not support these specific plans, are there alternative case study designs the Council recommends?

~~18.~~20. Does the Council support the plan for a feasibility analysis for a hedonic property study for valuing the effects of nitrogen deposition/eutrophication effects in the Chesapeake Bay region, with the idea that these results might complement the Waquoit Bay analysis?

Chapter 8: Economic Valuation

~~19.~~21. Does the Council support the plans described in chapter 8 for economic valuation of changes in outcomes between the scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

22. EPA's current analytic blueprint calls for an expert-judgment project on VSL determination that would produce a probability distribution over the range of possible VSL values for use in the 812 project. EPA is not sure how much priority to give to this project. A much simpler alternative would be for EPA to specify a plausible range of VSL values. One option would be to use a range bounded by $1 million (based roughly on the lower bound of the interquartile range from the Mrozek-Taylor meta-analysis) and $10 million (based roughly on the upper bound of the interquartile range of the Viscusi-Aldy meta-analysis. This range would match that reflected in EPA's sensitivity analysis of the alternative benefit estimate for the off-road diesel rulemaking. The range would then be characterized using a normal, half-cosine, uniform or triangular distribution over that range of VSL values. EPA would then ask this Committee to review this distribution. This approach could be done relatively quickly, based on the reviews and meta-analyses commissioned to date, and would allow a formal probability analysis to proceed, without suggesting that the Agency is trying to bring more precision to this issue than is warranted by the available science.

~~20.~~ ~~Pursuant to SAB Council advice from the review of the first draft analytical blueprint, EPA reviewed a number of meta-analyses –either completed or underway– developed to provide estimates for the value of statistical life (VSL) to be applied in the current study. EPA plans to use VSL estimates from the Kochi et al (2002) meta-analysis to generate~~

~~the primary benefits estimates for this study. In addition, EPA plans to implement two particular adjustments to the core VSL value from Kochi et al (2002): discounting of lagged effects and longitudinal adjustment to reflect changes in aggregate income. Does the Council support these plans, including the specific plans for the adjustments described in chapter 8? If the Council does not support these plans, are there alternative data or methods the Council recommends?~~

23. Pursuant to SAB Council advice from the review of the first draft analytical blueprint, EPA reviewed a number of meta-analyses –either completed or underway– developed to provide estimates for the value of statistical life (VSL) to be applied in the current study. EPA plans to consult with the Council (and coordinate this consultation with the EEAC) on how best to incorporate information from the Kochi et al (2002) meta-analysis, other published meta-analyses [Mrozek and Taylor and Viscusi and Aldy], and recent published research to develop estimates of VSL for use in this study. In addition, EPA plans to implement two particular adjustments to the core VSL values: discounting of lagged effects and longitudinal adjustment to reflect changes in aggregate income. Does the Council support these plans, including the specific plans for the adjustments described in chapter 8? If the Council does not support these plans, are there alternative data or methods the Council recommends?

24. For the 812 Report, EPA has decided to perform a cost-effectiveness analysis of the Clean Air Act provisions using quality-adjusted life years as the measure of effectiveness. This is the standard approach used in medicine and public health and this type of analysis has previously been recommended by the SAB. Moreover, the recent NAS Report (2002) on benefits analysis discussed how this method could be applied to the health gains from air pollution control.

    a. Do you agree that QALYs are the most appropriate measure of effectiveness for this type of analysis? Would you suggest any alternative measures to replace or supplement the QALY measure? (This question relates to effectiveness measures, not monetary benefit measures as used in benefit-cost analysis).

    b. OMB has suggested that EPA plan a workshop with clinicians, social scientists, decision analysts and economists to examine how the specific diseases and health effects in the 812 Report should be handled with respect to longevity impact and health-related preference. Participants would have knowledge of the relevant clinical conditions, the related health preference studies, and the stated-preference literature in economics. The recent RFF conference has laid the groundwork for this type of workshop. Is there a superior approach to making sure that the CEA-QALY project is executed in a technically competent fashion and that the details of the work receive in-depth technical input in addition to the broad oversight provided by this Committee?

c. Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?

~~21. As described in charge question 18, EPA has recently incorporated an Alternative Estimate of benefits in several recent Office of Air and Radiation analyses. In addition to the alternative assumptions related to health effects estimation described in charge question 18, the Alternative Estimates in these analyses applied methods or assumptions for economic valuation which differ significantly from approaches used by EPA to generate base estimates. EPA seeks advice pertaining to the scientific and technical merit of four adjustments to EPA Primary Estimate methods incorporated in the recent Alternative Estimates, including:~~

~~a. An initial VSL derived by using only five contingent valuation (CV) studies from the larger set of 26 hedonic wage and CV studies used to generate Primary Estimates in the previous 812 studies~~

~~b. Age-based adjustment to the CV-based VSL estimate described above using Jones-Lee (1989) –but not Jones-Lee (1993)– which had the practical effect of reducing initial VSL for people aged 70 and above by 37 percent [note: this was the approach used for the recreational vehicle and the Clear Skies Initiative analyses, but not the most recent analysis of the proposed nonroad diesel vehicle rule]~~

~~c. Age-based adjustment to the CV-based VSL estimate described above using a statistical life-years approach which assumed that later life-years may have a higher per-year value than average life-years saved in the middle of the life span [note: this was the approach used in the analysis of the proposed nonroad diesel vehicle rule]~~

~~d. Use of a cost of illness estimate based on Cropper and Krupnick (1990) to estimate the value of avoided chronic bronchitis, rather than the willingness to pay estimates used to generate Primary benefit estimates in the previous 812 studies~~

~~22. Does the Council support the derivation of VSLY values based on the life expectancy of the general population for application to individual loss of life years in individuals with greatly reduced life expectancy relative to the general population? If the Council does not support this approach, are there any life years-based valuation methods that the Council finds to be consistent with a standard welfare economics-based cost-benefit analysis?~~

~~23.~~25. EPA plans to use updated unit values for a number of morbidity effects, as described in chapter 8. Of particular note, EPA plans to rely on a study by Dickie and Ulery (2002) to provide heretofore unavailable estimates of parental willingness to pay to avoid respiratory symptoms in their children. This study is not yet published and has limitations concerning response rate and sample representativeness; however, EPA expects the study to be published prior to completion of the economic valuation phase of this analysis. Does the Council support the application of unit values from this study, contingent on its acceptance for publication in a peer-reviewed journal? If the Council does not support reliance on this study, are there other data or methods for valuation of respiratory symptoms in children which the Council recommends?

~~24.~~ ~~In the previous prospective 812 study and in the June 2001 draft blueprint for the current study, EPA expressed a preference not to report results in terms of QALY-based cost-effectiveness. This preference was motivated primarily by (1) the lack of generally accepted data and methods applicable to QALY computation in an air pollution context, (2) potential biases in the implicit cost-effectiveness results caused by incomplete netting out of other health and ecological benefits from the numerator, (3) concerns about the distortionary effect of the simplifying assumptions pertaining to time and quality trade-offs required to estimate QALYs, and (4) the general disconnect between available QALY methodologies and standard economic utility theory. In addition, EPA is seriously concerned about the requirement imposed by the QALY methodology to assign lower values to the lives, and the quality of the lives, of people of advanced age and/or impaired health status. However, the SAB Council in its review of the June 2001 draft blueprint recommended that EPA consider reporting results in terms of implied cost-effectiveness using QALYs or value of statistical life year (VSLY). Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint, including the plan to present these results in a less-prominent manner than the benefit-cost-based Primary results (e.g., in a main report sidebar text box or an appendix)? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?~~

Chapter 9: Uncertainty Analysis

~~25.~~26. Does the Council support the plans described in chapter 9 for estimating and reporting uncertainty associated with the benefit and cost estimates developed for this study? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

~~26.~~27. Does the Council support the plans described in chapter 9 for the pilot project to develop

probability-based estimates for uncertainty in the compliance cost estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in cost estimates for this analysis which the Council recommends?

~~27.~~28. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the emissions and air quality modeling estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in emissions and/or air quality concentration estimates for this analysis which the Council recommends?

~~28.~~29. Does the Council support the plans described in chapter 9 for the expert elicitation pilot project to develop a probability-based PM2.5 C-R function for premature mortality, including in particular the elicitation process design? If the Council does not support the expert elicitation pilot project, or any particular aspect of its design, are there alternative approaches the Council recommends for estimating PM-related mortality benefits for this analysis, including in particular a probabilistic distribution for the C-R function to reflect uncertainty in the overall C-R function and/or its components?

~~29.~~30. EPA plans to develop estimates of an independent mortality effect associated with ozone, as described in chapter 9. Does the Council support the use of the most recent literature on the relationship between short-term ozone exposure and daily death rates, specifically that portion of the literature describing models which control for potential confounding by PM2.5? Does the Council agree with the use of that literature as the basis for deriving quantified estimates of an independent mortality impact associated with ozone, especially in scenarios where short-term PM2.5 mortality estimates are used as the basis for quantifying PM mortality related benefits? Does the Council support the plans described in chapter 9 for the pilot project to use this literature to develop estimates of the ozone-related premature mortality C-R function using the three alternative meta-analytic approaches? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying ozone-related premature mortality which the Council recommends?

~~30. EPA plans to apply the Kochi et al (2002) meta-analysis to derive an initial value for VSL, as described in Appendix H (a separate charge question pertaining to this element of EPA's VSL plan is presented below). In addition, EPA plans to conduct a follow-on meta-regression analysis of the existing VSL literature to provide insight into the systematic impacts of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL. Does the Council support the plans described in chapter 9 for conducting this meta-regression analysis? If the Council does~~

~~not support this analysis or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the impact of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL?~~

31. EPA plans to work with the Council and the EEAC to develop revised guidance on appropriate VSL measures. We hope to include the Kochi et al (2002) meta-analysis, other recent meta-analysis, recent publications, and the 3 literature reviews sponsored by EPA.(a separate charge question pertaining to this element of EPA's VSL plan is presented below). In addition, EPA plans to conduct a follow-on meta-regression analysis of the existing VSL literature to provide insight into the systematic impacts of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL. Does the Council support the plans described in chapter 9 for conducting this meta-regression analysis? If the Council does not support this analysis or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the impact of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL?

~~31. Does the Council support the plans described in chapter 9 for, if necessary upon review and evaluation of the VSL meta-regression, conducting a formal expert elicitation analysis to develop probabilistic representations of the distribution of the value of a statistical life, with the potential for separate distributions developed for individual age groups, and considering potentially influential variables, such as risk characteristics and health status, which may not be completely captured in the meta-regression? If the Council does not support this expert elicitation project, or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the influence of population or risk characteristics on the VSL estimates to be used in characterizing uncertainty for this study?~~

Chapter 10: Data Quality and Intermediate Data Products

32. Does the Council support the plans described in chapter 10 for evaluating the quality of data inputs and analytical outputs associated with this study, including the planned publication of intermediate data products and comparison of intermediate and final results with other data or estimates? If the Council does not support these plans, are there alternative approaches, intermediate data products, data or model comparisons, or other data quality criteria the Council recommends? Please consider EPA's Information Quality Guidelines in this regard.

Chapter 11: Results Aggregation and Reporting

33. Does the Council support the plans described in Chapter 11 for the aggregation and presentation of analytical results from this study? If the Council does not support these plans, are there alternative approaches, aggregation methods, results presentation techniques, or other tools the Council recommends?

Appendix D: Stratospheric Ozone Analysis

34. Does the Council support the plans described in Appendix D for updating the estimated costs and benefits of Title VI programs? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

Appendix E: Air Toxics Case Study

35. Does the Council support the plans described in Appendix E for the benzene case study, including the planned specific data, models, and methods, and the ways in which these elements have been integrated? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

36. A cessation lag for benzene-induced leukemia is difficult to estimate and model precisely due to data limitations, and EPA plans to incorporate a five-year cessation lag as an approximation based on available data on the latency period of leukemia and on the exposure lags used in risk models for the Pliofilm cohort (Crump, 1994 and Silver et al., 2002). Does the SAB support adoption of this assumed cessation lag? If the Council does not support the assumed five-year cessation lag, are there alternative lag structures or approaches the Council recommends?

Appendix H: Meta-analysis of VSL

37. ~~Does the Council support the plans described in the analytical blueprint to apply the Kochi et al (2002) meta-analysis to derive an estimate for the value of avoided premature mortality attributable to air pollution? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?~~

Does the Council support including the Kochi et al. (2002) meta-analysis as part of a the larger data base of studies to derive an estimate for the value of avoided premature mortality attributable to air pollution? Are there additional data, models, or studies the Council recommends? Does the SAB think that EPA should include Kochi et al. 2003 if not accepted for publication in a peer reviewed journal by the time the final 812 report is completed?