ADVISORY COUNCIL ON CLEAN AIR COMPLIANCE ANALYSIS

Health Effects Subcommittee (HES)

Review Background and Charge Questions

December 15-16, 2009 Meeting

Review Background

The section 812 benefit-cost studies of the Clean Air Act are a unique series of EPA analyses. Unlike routine Regulatory Impact Analyses (RIAs) which focus on the incremental effect of proposed new rules relative to a continually changing, prevailing policy baseline, the 812 studies are intended to evaluate the benefits and costs of the Clean Air Act as a whole relative to a consistent baseline, taking account of critical interactions between program elements and outcomes which are not captured by the generally isolated and incremental policy scenarios assessed in RIAs. In addition, Congress expressed their intent that the comprehensiveness of the 812 studies should encourage and enable EPA to develop and continually refine its capabilities in clean air program assessment. Congress' stated objective was to ensure EPA could provide better information on clean air program benefits and costs in support of the next round of Clean Air Act reauthorization, whenever that may occur.

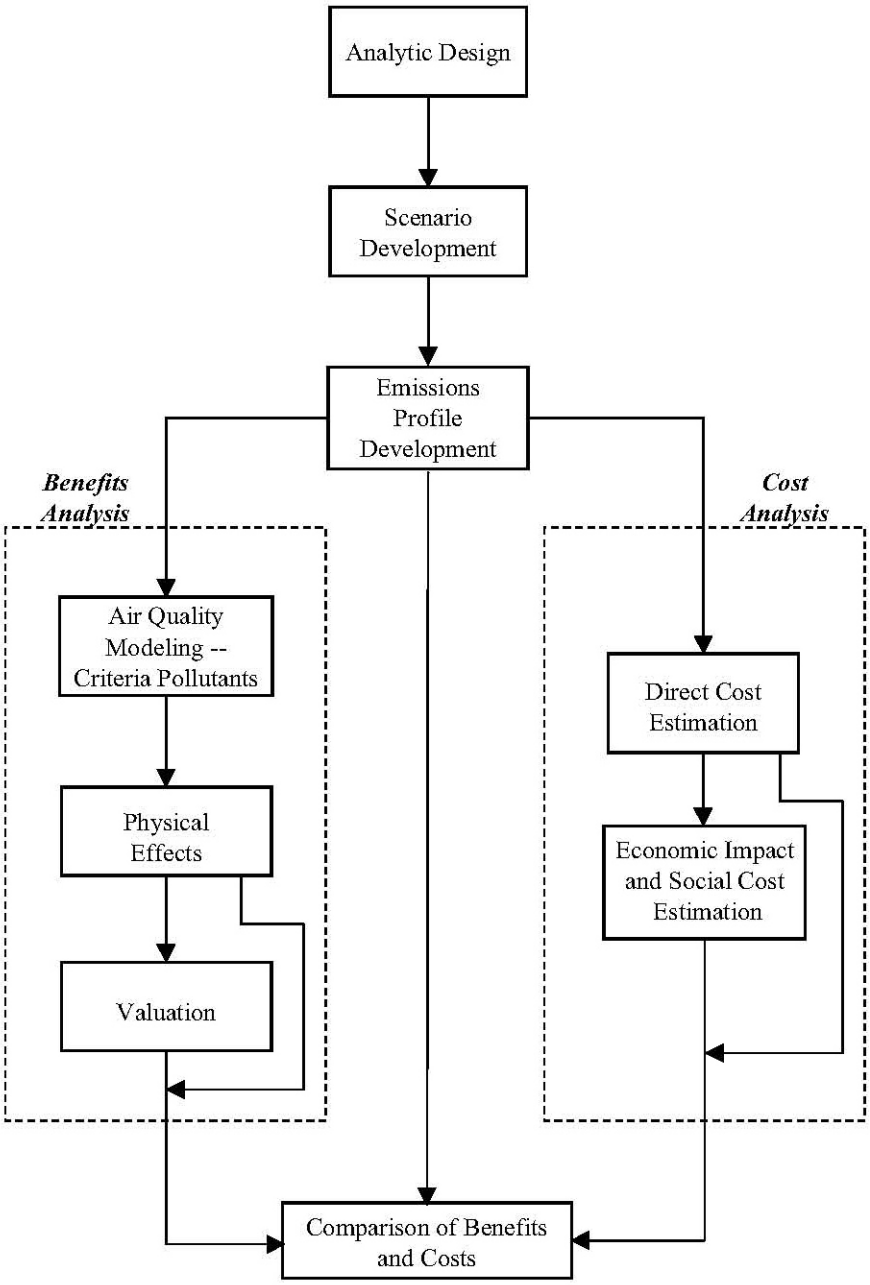
In response to section 812 requirements, EPA has published two studies as Reports to Congress: a Retrospective Study published in November 1997 examining the benefits and costs of the 1970 Clean Air Act and the 1977 Amendments from the period 1970 to 1990, and a First Prospective Study published in October 1999 which evaluated the incremental effects of 1990 Clean Air Act Amendment programs from 1990 to 2010. Currently, EPA's 812 Project Team is nearing completion of the analytical work for a study which updates and extends the First Prospective Study. This new study, commonly referred to as the Second Prospective Study, is similar in scope and design to the First Prospective Study, but incorporates many of the major programs promulgated since the 1999 publication of the First Prospective, applies more up-to-date scientific and economic information, and evaluates effects out to the year 2020.

A particularly important feature of the section 812 studies is the scope, timing, and quality of outside expert review. Section 812 of the Amendments required EPA to convene a panel of outside experts in a range of relevant disciplines to advise the Administrator on the data chosen for the analysis, the selection of models used to conduct the analysis, and the validity and utility of the resulting estimates of Clean Air Act program benefits and costs. EPA is unaware of any similarly comprehensive assessment of government programs which involves such rigorous *ex ante* review of planned methodologies and *ex post* review of analytical results. The quality of the outside expert reviews conducted throughout the series of studies has immensely improved all three studies, enabling EPA to meet the Congressional objectives of improved EPA analytical capabilities and deeper insights into the effects of Clean Air Act programs.

Organized under the auspices of EPA's Science Advisory Board (SAB), the statutorily-prescribed Advisory Council on Clean Air Act Compliance Analysis (Council) was established in 1991 to provide this multi-disciplinary outside expert review. Subsequently, separate subcommittees were established to advise the parent Council on particular technical aspects of the studies. The Air Quality Modeling Subcommittee (AQMS) was formed to advise the Council on issues of emissions estimation, air quality modeling, and some aspects of exposure modeling. Initially, a single subcommittee was formed to advise the Council on issues associated with estimation of physical effects, including those related to both human health and environmental outcomes. This subcommittee was named the Physical Effects Review Subcommittee (PERS). Later, the name of this subcommittee was changed to the Health and Environmental Effects Subcommittee (HEES), though the disciplinary scope of its review responsibilities remained the same. Eventually, this subcommittee was split into the two separate subcommittees in place today: the Health Effects Subcommittee (HES) responsible for advising the Council on human health effects estimation and the Ecological Effects Subcommittee (EES) responsible for advising the Council on issues associated with estimation of ecological consequences.

To facilitate the *ex ante* review of planned methodologies for the Second Prospective Study, the 812 Project Team published an "analytical blueprint." An initial draft blueprint was developed by the 812 Project Team and submitted for Council, AQMS, HES, and EES review in 2001. Pursuant to the Council's advice, significant revisions were made to the analytical blueprint, and a final version was published in 2003. Following the May 2004 publication of the Council's review of the revised analytical blueprint, the Project Team initiated the analysis.

The core analytical sequence for the Second Prospective Study is summarized in the following exhibit adapted with a slight modification from the May 2003 final analytical blueprint:



This sequence of analytical components is used to estimate the differences in economic, health, and environmental outcomes between two "core scenarios." The first core scenario, which serves as the analytical baseline, is the "*without-CAAA90*" case. This scenario freezes Clean Air Act and related State and local programs at the levels of scope and stringency which prevailed in November 1990 when the 1990 Amendments were passed, while allowing the population and economy to grow. The core scenario which is contrasted with this baseline case is the "*with-CAAA90*" scenario. For the historical years of the study's 1990 to 2020 reference period, the *with-CAAA90* case reflects actual CAAA program implementation. For future years,

the *with-CAAA90* reflects the Project Team's judgment at the time the scenarios were locked regarding the future implementation of Clean Air Act programs. It is the estimates for the incremental change in benefits and costs moving from the *without-CAAA90* case to the *with-CAAA90* case during the 2000, 2010, and 2020 target years which represent the principal analytical outputs of the Second Prospective Study.

In addition to the principal results provided by the core scenarios analysis, a number of supplemental analyses were conducted to provide additional information about Clean Air Act program costs and benefits. These supplemental analyses, which are all complete or nearing completion, include:

1. a Hazardous Air Pollutant (HAP) benefits case study, which focused on evaluating the effect of the 1990 Clean Air Act Amendments on benzene emissions and subsequent exposure and risk changes in the Houston MSA,

2. an ecological effects case study, which focused on estimation of changes in Adirondack lake acidification and resulting improvements in ecological service flows, as well as characterizing potential effects on standing timber, and

3. a computerized general equilibrium (CGE) analysis assessing the broader economic consequences of the changes in direct compliance expenditures and, to a limited extent, in population health and productivity resulting from 1990 CAA Amendment programs.

Each major component of the core scenarios analysis and each key supplemental analysis have been, or will soon be, documented in a standalone report. These standalone reports provide detailed descriptions of the methodologies and results for each analytical component, and it is these component-specific reports which have provided the focus for review by the Council and its technical subcommittees. In early 2010, a single integrated report documenting the overall Second Prospective Study will be drafted and submitted to the Council for review.

As of today, the planned methodologies and, in many cases, the results of the core scenario analysis components and the supplemental analyses have been reviewed by the relevant Council panels. Final review meetings for each of the panels are planned for late 2009 and early 2010. Current plans for the timing and key objectives for each of these panel meetings are as follows:

1. **HES.** December 15-16, 2009.

    a. Review the draft human health effect primary estimates incorporated in relevant chapters of the draft standalone benefits report.

    b. Review the human health components of the draft standalone uncertainty analysis report.

c. Provide advice to the Council regarding the validity and utility of the draft human health effects estimates and several final analytical choices pertaining to the health effect analysis and uncertainty analysis.

2. **AQMS.** 2010-Second Quarter.

a. Review the final standalone air quality modeling report.

b. Provide advice to the Council regarding the validity and utility of the final estimates of air quality concentration changes.

3. **EES**. 2010-Second Quarter.

a. Review the final updated ecological effects literature review and the ecological effects case study report.

b. Provide advice to the Council regarding the validity and utility of the literature review and ecological effects case study.

4. **Council**. 2010-Third Quarter.

a. Review the draft integrated report documenting all aspects of the Second Prospective Study, taking account of the final advisory recommendations of the technical subcommittees.

November 2010 is the 20th anniversary of the passage of the 1990 Clean Air Act Amendments. EPA has set a goal to complete the Second Prospective Study in time for its results to inform discussions and other activities associated with the 20th anniversary of the Act's most recent amendments.

The remainder of this document describes key considerations related to Council subcommittee review scope and process, lists the documents being submitted for Council HES review, and presents the review charge questions which EPA respectfully submits to the Council HES for consideration.

Review Scope and Process

Consistent with the statutorily-defined role of the Council and consistent with longstanding precedent in the conduct and review of the 812 studies, EPA proposes two types of charge questions. The first questions are general and conform to the particular requirements for review statutorily prescribed in section 812. Given their wide-ranging scope and generality, Council review panels have traditionally and properly interpreted these general charge questions as an invitation to review and consider rendering advice on any aspect of the analytical design, implementation, and results which may be considered appropriate by the panel chair.

The general charges are usually supplemented with more specific questions from the Project Team. These specific questions are typically motivated by the Project Team's need for advice from a panel on a particularly controversial and/or highly significant methodological choice. For example, the charge questions presented below include a request for advice from the HES regarding the Project Team's current plan to use the Pope et al. 2002 ACS follow-up study as the basis for the Primary Estimate of the change in incidence of PM-related premature mortality.

Both types of charge questions are configured by EPA to be as consistent as possible with the statutorily-defined advisory –as opposed to co-authorship—role of the Council and its technical subcommittees. In particular, charge questions are typically formulated to elicit advice from the Council on analytical choices already adopted, at least tentatively, by the Project Team. In many cases these analytical choices already conform to –or at least take account of—advice rendered by a previous Council panel during review of the analytical blueprint or during one of the interim reviews conducted since the Second Prospective Study began. In other cases, these analytical choices may have changed since the analytical blueprint was published based on emerging literature and/or relevant advice from other qualified panels such as those convened by the National Academy of Sciences. Nevertheless, every analytical choice reflected in the materials submitted for Council and Council subcommittee review is "fair game" for consideration and advice, though EPA by statute and tradition retains ultimate responsibility for all final analytical choices manifest in the section 812 studies.

Another factor which influences how the charge questions are configured is the organizational relationship between the Council and its technical subcommittees. Specifically, as a formal matter the technical subcommittees have all been chartered to provide advice to the Council, which retains exclusive authority and responsibility for rendering formal advice to the Agency. The Council, however, has consistently encouraged direct engagement between the technical subcommittees and the 812 Project Team during public review meetings such as the one scheduled for December 15-16, 2009. This direct engagement is also consistent with the point in the previous paragraph that the responsibility for all analytical choices ultimately resides solely with EPA.

Finally, the chapters and appendices submitted for review to the Council HES incorporate other analytical methods and choices apart from those associated with the HES' responsibilities to provide advice on human health effects estimation. For example, the draft benefits report chapter documenting the human health effects incidence estimates also presents draft results for the economic valuation of those incidence changes. However, review of the analytical choices pertaining to economic valuation of effects is primarily the responsibility of the parent Council. It is likely that the Council would be interested in any advice the HES chooses to convey regarding any analytical issue linked to the human health effects estimates; however, the HES is under no obligation to review elements of the review documents which the HES chair considers more appropriately managed by the Council or one of the other Council subcommittees.

Review Documents

The following documents are submitted for review and consideration by the Council HES during the December 15-16, 2009 meeting.

1. Industrial Economics Incorporated, "Benefits Analyses to Support the Second Section 812 Benefit-Cost Analysis of the Clean Air Act – Draft", prepared for the US EPA Office of Air and Radiation, November 13, 2009.

    a. Chapter 1: Introduction *[7 pages]*

    b. Chapter 2: Estimation of Human Health Effects and Economic Benefits *[46 pages]*

2. Industrial Economics Incorporated, "Uncertainty Analyses to Support the Second Section 812 Benefit-Cost Analysis of the Clean Air Act - Draft", prepared for the US EPA Office of Air and Radiation, November 13, 2009.

    a. Chapter 1: Introduction *[9 pages]*

    b. Chapter 4: Concentration-Response Function Uncertainty *[10 pages]*

    c. Chapter 5: Differential Toxicity of PM Components *[21 pages]*

    d. Chapter 6: Particulate Matter/Mortality Cessation Lag *[12 pages]*

    e. Chapter 7: Dynamic Population Modeling *[10 pages]*

    f. Appendix C: Table C-4. Key Uncertainties Associated with Human Health Effects Modeling, pp. C-8 to C-12 *[5 pages- full appendix is 14 pages]*

In addition to these documents submitted for formal review, the Project Team is providing the following additional materials to facilitate the Council HES review.

1. Abt Associates, 2008. *Environmental Benefits Mapping and Analysis Program (BenMAP) User's Manual Appendices.* Prepared for EPA/OAR/OAQPS, September 2008.

2. Industrial Economics Incorporated, *Alternative Presentation of PM Expert Elicitation Results, Presentation to EPA Science Advisory Board 812 Council Health Effects Subcommittee*, December 15, 2009.

3. Technical Memorandum from Neal Fann, OAR/OAQPS to Jim DeMocker, OAR/OPAR, *Estimating $PM_{2.5}$ and Ozone-related Premature Mortality Based on Risk Estimates from the Jerrett et al. (2009) and Krewski et al. (2009) Studies*, November 15, 2009. *[7 pages]*

4. Industrial Economics Incorporated, *ibid.* Draft Uncertainty Report, Appendix A: Qualitative Uncertainty Analysis Tables From The First Prospective Analysis , Table A-4, pp. A-10 to A-14, November 13, 2009. *[5 pages- full appendix is 19 pages]*

Review Charge Questions

1. General Charge. EPA requests that the Council HES review the human health-related chapters and appendices of the draft Section 812 Second Prospective Study benefits and uncertainty reports. Consistent with the statutory language defining the role of the Council in reviewing the 812 studies—and consistent with the role of the HES as advisor to the Council on human health effect estimation—EPA respectfully submits the following general charge questions to the HES:

    a. Does the Council HES support the data choices made by the 812 Project Team for the development of the human health-related chapters and appendices of the draft benefits and uncertainty reports? If not, are there alternative data sets the Council HES recommends should be applied instead?

    b. Does the Council HES support the methodological choices made for analyzing those data and developing the human health effect estimates for the relevant scenarios, and for characterizing their uncertainty? If not, are there alternative methodologies the Council HES recommends should be applied instead?

    c. What advice does the HES have for the Council regarding the validity and utility of the human health effect analyses incorporated in the draft benefits report and the uncertainty analyses incorporated in the draft uncertainty report? If the validity and/or utility of the reports and their underlying analyses could be improved, what specific improvements does the Council HES recommend that the 812 Project Team consider, either for the present analysis or as part of a longer term research and development program?

2. Specific Charges. The general charge question #1 covers any and all aspects of the draft benefits report which the Council HES might consider appropriate to address in its review. In conducting this review, EPA also respectfully requests that the Council HES consider the following analytical choices made by the 812 Project Team and manifest in the draft reports submitted for review. Consistent with the scope and process for review pursuant to the General Charge, for each of these analytical choices EPA requests that the Council HES consider providing advice regarding the reasonableness of the analytical choice made by the Project Team. If the Council HES does not support the analytical choice made by the Project Team, EPA respectfully requests that the Council HES identify one or more appropriate alternative approaches. In describing such alternatives, EPA requests that the Council HES indicate whether such alternative is likely to be feasible for application in the Second Prospective Study according to its current schedule or whether such potential improvement should be viewed as a subject for longer-term research and potential application in future studies.

    a. PM Mortality Concentration-Response Function (CRF). The current draft benefits report reflects adoption of the Pope et al. 2002 study as the basis for the Primary Estimates of the difference in incidences of PM-related premature mortality. Also within the main benefits report, an Alternative Estimate is presented prominently

which is based on the Laden et al. 2006 study. Furthermore, the Project Team is currently assessing the potential significance of the recent Krewski et al. (2009) publication since it appears to strengthen the evidence for PM-related Ischemic heart disease and lung cancer mortality and could provide the basis for a revised Primary Estimate or an additional Alternative Estimate. Uncertainty in the Primary Estimate is further described in the draft uncertainty report through graphical presentation of results obtained by applying each of the 12 expert elicitation study functions to the differences in PM exposure estimated for the *with-CAAA90* and *without-CAAA90* core scenarios. In addition, the Project Team has recently been considering an approach developed by Industrial Economics which uses a Copula function to generate results representing the 12 expert functions. This approach is summarized in a draft briefing which the Project Team proposes to present to the HES on December 15 for its consideration.

> Does the Council HES support these study selections and the organization and presentation of PM mortality estimates in the draft benefits and uncertainty reports? In addition, a particular question for which the Project Team seeks HES advice is whether the application of mortality risk coefficients drawn from the Krewski et al. (2009) study should be considered for use in generating the Primary Estimate, or at least as the foundation for an Alternative Estimate. If the answer to either, or both, of these two questions is negative, are there alternative study choices and/or methods for generating, organizing, and presenting results which the Council HES recommends EPA consider?

b. <u>PM Mortality Cessation Lag Function</u>. The Primary Estimates for PM mortality reflect an assumed lag between cessation of exposure and realization of the change in health effect incidence. Based in part on prior Council HES advice, the primary estimates in the draft benefits report reflect a 20-year distributed lag. Specifically, 30 percent of the total reduced incidences is assumed to occur in the first year following the exposure change. Another 50 percent of the total incidence changes is assumed to be spread evenly over years two through five. The remaining 20 percent of the incidence change is spread evenly over years six through twenty. The effect of the cessation lag is realized through discounting (at a 5 percent rate) of the monetized value of future-year incidence changes (i.e., there is no need, and no intent, to represent the discounted values as reflecting direct discounting of incidences *per se*). In addition, the draft uncertainty report evaluates the effect of alternative lag structures. These alternatives include the 5-year distributed lag applied in the First Prospective Study and a set of smoothed lag functions derived from consideration of the results of available cohort and intervention studies.

> Does the Council HES support the use of the 20-year distributed lag structure described above for generation of the Primary Estimates of the monetary value of PM mortality incidence reduction and the specific alternative lag functions presented in the draft uncertainty report? If not, are there alternative study choices and/or methods for organizing and presenting results which the Council HES recommends EPA consider?

c. PM Infant Mortality. EPA's current approach to estimating the association between PM exposure and respiratory inflammation and infection leading to premature mortality in children under 5 years of age relies on the cohort study conducted by Woodruff et al. (1997). This is based in part on prior (SAB-HES) advice, which noted several strengths of the study, including the use of a larger cohort drawn from a large number of metropolitan areas and efforts to control for a variety of individual risk factors in infants (e.g., maternal educational level, maternal ethnicity, parental marital status, and maternal smoking status). A more recent study by Woodruff et al. (2006) continues to find associations between $PM_{2.5}$ and infant mortality, and also found the most significant relationships with respiratory-related causes of death.

> Does the Council HES recommend continued reliance on the Woodruff et al. (1997) study to characterize the association between PM exposure and respiratory inflammation and infection leading to premature mortality in children under 5 years of age, or recommend that the relationship be characterized by the more recent Woodruff et al. (2006) study, or recommend some other approach that relies on a third study or some combined consideration of multiple studies? Are there specific reasons to favor the results of one of these studies or of another study?

d. PM Mortality Effect Threshold. Consistent with prior SAB and NAS advice, the Project Team did not attempt to alter the Pope 2002 CRF to reflect an assumed concentration threshold below which PM concentration changes would yield no change in estimated incidences. In addition to the lack of compelling evidence for any particular effects threshold, the Project Team is not aware of any valid procedure for the altering the CRF above an assumed threshold. In other words, the Project Team presumed that imposition of an (arbitrary) threshold would require respecification of the CRF to ensure a "with threshold" CRF slope that would accurately account for the total change in incidence expected based on the epidemiological study from which the CRF was derived. Prior efforts to apply a threshold simply truncated the incidence change estimated from a no-threshold CRF, though prior SAB advice indicates this is improper and the Project Team chose not to apply such an adjustment in the current analysis.

> Does the Council HES support the use of a no-threshold model for generation of the Primary Estimates of PM mortality incidence reduction? If not, are there methods for estimating and applying an effects threshold which the Council HES recommends EPA consider, either for the Primary Estimates or for presentation in the draft uncertainty report?

e. Ozone Mortality CRF. Based in part on prior SAB and NAS advice, EPA has included changes in ozone-related premature mortality as part of the Primary Estimate of benefits in the draft benefits report. Recognizing the ongoing uncertainty regarding the appropriate study or studies from which a quantitative CRF should be derived, the Project Team adopted a placeholder function for the Primary Estimate of changes in ozone mortality which encourages focus on several key factors: study selection, pooling across studies, and pooling methodology. Given the particular uncertainties regarding the reasonableness of pooling across the multi-city NMMAPS

studies and the meta-analyses, the Project Team specified a CRF for the Primary Estimate which reflects inverse variance-weighted pooling of the Bell et al. 2004 and Schwartz 2005 mortality effect estimates, both of which reflect an all-cause mortality endpoint. In addition, the draft uncertainty report presents alternative results obtained by applying CRFs derived from each of the three individual multi-city time-series studies and three meta-analyses. Furthermore, EPA has developed an alternative CRF based on the Jerrett et al. (2009) long-term ozone mortality study. This approach is described in the technical memorandum included in the package of review documents.

> Does the Council HES support the use of the ozone mortality CRF derived by pooling the Bell et al. 2004 and Schwartz 2005 studies for the Primary Estimate and the presentation of the six alternative estimates in the draft uncertainty report? A particular question for which the Project Team seeks HES advice is whether application of the respiratory mortality risk estimate drawn from Jerrett et al. (2009) might be suitable for use in generating the Primary Estimate, or at least for generation of an Alternative Estimate. If the answer to either, or both, of these two questions is negative, are there alternative study selection and/or pooling approaches the Council HES recommends EPA consider for the Primary Estimate in the draft main benefits report and/or for the Alternative Estimates presented in the draft uncertainty report?

f. Ozone Mortality Cessation Lag. Based on a perceived lack of empirical data to support specification of a cessation lag structure for ozone-related mortality effects, the Project Team has not attempted to apply a cessation lag structure for the Primary Estimate of ozone mortality reduction benefits in the draft benefits report, nor are alternatives evaluated in the draft uncertainty report.

> Does the Council HES support the use of a no-lag assumption for the Primary Estimate of ozone mortality benefits presented in the draft benefits report? If not, are there methods for estimating and applying a cessation lag structure for ozone mortality which the Council HES recommends EPA consider, either for the Primary Estimates or for presentation in the draft uncertainty report?

g. Ozone Mortality Effect Threshold. Based on a perceived lack of empirical data to support application of a concentration threshold for ozone-related premature mortality effects, the Project Team did not attempt to apply an effect threshold for the Primary Estimate of ozone mortality reduction benefits.

> Does the Council HES support the use of a no-threshold model for generation of the Primary Estimates of ozone mortality incidence reduction? If not, are there methods for estimating and applying an effects threshold which the Council HES recommends EPA consider, either for the Primary Estimates or for presentation in the draft uncertainty report?

h. Baseline Incidence / Prevalence Estimates. Baseline incidence / prevalence are key determinants of the estimated changes in health effect incidence described in the draft benefits and uncertainty reports.

Does the Council HES support the choices made by the Project Team regarding baseline incidence / prevalence across the various human health endpoints incorporated in the Primary Estimate of benefits? If not, are there alternative baseline incidence / prevalence data which the Council HES recommends EPA consider, either for the Primary Estimates or for presentation in the draft uncertainty report?

i. PM Differential Toxicity Sensitivity Analysis. In its review of the Second Prospective Study analytical blueprint, the Council recognized that the state of the science did not support development and application of assumptions regarding the potential differential toxicity of PM components suitable for informing the present analysis. However, the Council did encourage the Project Team to explore the feasibility of conducting a sensitivity analysis to gauge the potential significance of differential toxicity. After extensive review of the literature and analysis of options, the Project Team concluded that currently available data and methodologies remain insufficient to meet the challenge of developing a reasonably valid and usefully informative sensitivity analysis, even on a notional basis. Indeed, the Project Team concluded that the potential research utility of such a sensitivity analysis in the end did not appear to justify the risks from potential misinterpretation and misapplication of the results of such a sensitivity analysis. The Project Team's evaluation of the issue of differential toxicity is presented in chapter 5 of the draft uncertainty report.

Does the Council HES support the Project Team's decision to defer quantitative sensitivity analysis of potential PM component differential toxicity? If not, are there data or methods for conducting a quantitative analysis of PM component differential toxicity which the HES recommends EPA consider, or are there other aspects of differential PM component toxicity which the HES recommends should be addressed in the draft benefits and/or uncertainty reports?

j. Dynamic Population Modeling. Chapter 7 of the draft uncertainty report describes the results of the Project Team's application of a dynamic population simulation model to the evaluation of changes in pollution-related premature mortality risks. The Project Team continues to consider the potential utility of dynamic population modeling approaches and respectfully requests that the HES review the methodology and results and consider providing advice regarding the potential utility of further development and future application of this approach.

Does the Council HES have recommendations regarding the potential value for future analyses of the dynamic population approach described in chapter 7, or any alternative approaches the HES may suggest for addressing the issue of population changes during a study's reference period?

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