July 28, 1999

EPA-SAB-COUNCIL-ADV-99-012

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

RE: The Clean Air Act Amendments (CAAA) Section 812 Prospective Study of Costs and Benefits (1999): Advisory by the Health and Ecological Effects Subcommittee on Initial Assessments of Health and Ecological Effects; Part 1

Dear Ms. Browner:

On April 20-21, 1999, the Health and Ecological Effects Subcommittee (HEES) of the Advisory Council on Clean Air Compliance Analysis (Council) met to provide advice on seven charge questions relating to the health and ecological effects associated with implementation of the 1990 Clean Air Act Amendments (CAAA of 1990, Section 812, Public Law 101-549, November 15, 1990, 104 Stat. 2399) projected to the year 2010. The Subcommittee reviewed draft material and received briefings from Agency staff and contractors. The HEES will meet again on June 28-29, 1999 to advise on several additional questions to assist the Agency in completing its effects assessment. After that meeting, the HEES will complete Part 2 of this Advisory.

This HEES Advisory for the Prospective Study provides comment on the draft health and ecological assessments provided for review and the degree of uncertainty or certainty associations with the individual tasks necessary to complete the current Study. The recommendations are designed to strengthen the health and ecological assessments that will provide the basis for the cost and benefits analysis in this year's Prospective Study. The Council will review the draft Study at its meeting on July 13-14, 1999, pursuant to the requirements of the CAAA.

This Advisory also identifies gaps in information, data, and methods that need to be filled to strengthen future Prospective Studies, which the CAAA require to be submitted to Congress every two years. The study will be the first attempt at a prospective analysis. It is expected that the comprehensiveness of the analysis will increase over time, especially as further research becomes available for use in model simulations of emissions, exposure, health and ecological effects, and costs and benefits.

Response to Charge Questions

Charge Question 1. EPA requests SAB review of our ecological assessment framework. In particular, EPA has incorporated in the 812 report extensive discussion of: major stressors from air emissions subject to control under the CAAA and a broad range of possible impacts on ecosystem structure and function. EPA also requests review of our clarification of the selection process for identifying those elements of ecological impacts that we find suitable to quantify and monetize, based on the level of understanding of the effect and the ability to develop a defensible causal link between changes in air pollution emissions and specific ecological impacts.

Response. The narrative about ecological processes in Appendix E is a positive step forward for the Section 812 Prospective Study. An ecological perspective and a better integration of economics and ecology are now more evident, yet several issues remain.

Framework Issues. The introduction and the sections addressing individual pollutant categories provide a much better ecological perspective than was presented in previous Section 812 documents reviewed by the HEES. Even so, we believe that Appendix E should give more attention to a systems perspective. We recommend that readers be introduced to the concept that important ecological effects such as population decline of a keystone species can ripple through a food web and alter community structure and ecosystem function. This important principle could be added to the first bullet on page E-1 as an example of ecological complexity and non-linearity.

In addition, the EPA has minimized the discussion of the value of large-scale system processes (e.g., at the watershed scale) that have not yet been quantified well in ecological studies. Although tools may not currently be available to model and monetize indirect and complex effects of air pollutants, explicit presentation of such fundamental ecological concepts early in this Section 812 Prospective Study will help to advance the systems approach in future Prospective Studies.

Selection of Monetizable Pathways. Although the Methodological Overview (p. E-16) now presents a clearer, direct statement of the criteria for selecting impacts that are amenable to quantitative benefits analysis, we note several limitations. In choosing the impacts categories, the EPA appears to have adopted an understandably conservative stance to minimize Type I errors. Moreover, the limited availability of data and tools to form links in and between the fields of ecology and natural-resource economics have forced EPA to adopt an opportunistic approach to selecting service flows. The Agency's approach does not focus on service flows that in concept might have the highest monetized benefits because sufficient information and tools are not available. This is a limitation of the Prospective Study that reflects a general lack of ecological and economic studies directed toward monetizing the benefits of reducing pollution. The limitation can only be overcome through a concerted research effort funded by EPA, other agencies, or industry. Thus, it would be useful for the Section 812 Project Team to identify the potentially most important ecological service flows and to delineate the critical data and modeling information needed to monetize these key service flows.

The choice of acidic deposition (sulfuric and nitric acids), nitrogen, mercury, dioxins and tropospheric ozone as the primary pollutants in this analysis was well justified and well reasoned. Ecological benefits for control of lead are not included for the obvious reason that the Agency's ban of lead additives in gasoline vastly reduced lead emissions. None the less, some emission sources remain, and lead particles are constantly being re-entrained due to forces such as wind and traffic. Unfortunately, the ecological benefits of lead reductions under the CAA were not monetized during the Section 812 retrospective study. Thus, monetized ecological benefits of reducing lead emissions appear to have fallen into a crack between the retrospective and prospective studies. To fully evaluate past and present air pollution control benefits, ecological benefits of control of lead will have to be addressed in this or a future Prospective Study.

Charge Question 2. EPA requests review of other modifications incorporated in the ecological evaluation approach.

Issue 2.1. Qualitative characterization of interaction between air toxics and acidification in aquatic systems.

Response. One of the major interactions between air toxics and acidification alluded to in a previous HEES report was that acidification can alter the bioavailability of metals and polar organic pollutants in aqueous systems, thus producing indirect ecological effects of air pollution on other pollutants that might or might not have been deposited in the aqueous system as a result of air pollution.

Nitrogen deposition can also interact with air toxics. Increased nitrogen deposition can lead to eutrophication of surface waters and generally results in a lower redox potential in sediments in lakes, wetlands, and estuaries. In turn, these more strongly reducing sediments can alter the fate of pollutants by increasing or decreasing their rates of transformation to less toxic (or sometimes more toxic and persistent) forms. Although the degree to which complex, nonlinear interactions among air toxics, acidification, and nitrogen deposition occur depends on site-specific water and sediment chemistry, the interactions can be expected to alter the toxicity of mercury and other air toxics.

Issue 2.2. Quantitative accounting for lag times in the acidification analysis and qualitative characterization in other parts of the analysis.

Response. The analysis of lag times in other parts of the Prospective Study (e.g., terrestrial ecosystems, watershed, and economics) is relegated to a qualitative presentation. Although time and resource constraints may dictate this approach, the ecological community has moved progressively towards longer-term consequences in lieu of analyses that focus on short time horizons. Considerable progress will be needed to develop a tool for the quantification of long-term ecological impacts including lag times, and the committee recommends this as a high priority. We suggest that within the current Prospective Study, the Agency should identify research and analytical steps that need to be taken to provide a more quantitative, ecologically relevant approach for future Prospective Studies.

Issue 2.3. Quantitative consideration of nitrogen saturation of terrestrial ecosystems.

Response. A recent HEES Advisory (EPA-SAB-ADV-99-005) suggested the Agency address nitrogen saturation. The reason for the request was several fold, but largely was based on the potential for nitrogen (N) deposition from the atmosphere to serve as a "fertilizer" over broad geographical areas (forest, crops, watershed). The consequence of this N addition is not truly a fertilizer effect but rather one in which a rate-limiting nutrient (N) changes the biotic and abiotic interactions. The expectation is for changes in N deposition to be reflected in changes in species competitiveness and soil chemistry leading to changes in surface water chemistry and species diversity. This issue (N deposition) is a touchstone in the ecological community and ranks in the top five items on the ecological research agenda for the coming decade.

The Agency responded with a qualitative statement in the draft analysis. The decision not to provide a quantitative assessment of N deposition effects in the Prospective Study is unfortunate. A host of analyses could be brought to bear both in qualitative and quantitative terms.[1] A notable example is the well-documented analysis that establishes critical N inputs to soils that result in long-term changes in soil chemistry. In addition, the broad-scale N deposition that serves as a N source to forests and crops and attendant effects on carbon sequestration are absent from the analysis.

While time and resources are scarce to do justice to this component of the current Prospective Study, we recommend that the Agency lay the foundation to capture this issue in future Prospective Studies. That foundation needs to be tied to the literature and bring in state-of-the-art methodologies. A methodology that is based on GIS capabilities and that is linked to models of the atmosphere and biosphere would be extremely useful for this analysis.

Issue 2.4. Use of the PNET II model in place of the deSteiguer study for estimating the impacts of ozone exposure on commercial forest stands.

The HEES requested that the proposed approach (using deSteiguer's data) be reconsidered since it is dated, suspect in its ability to capture effects, inflates effects on forest (heavily weighted to the Southern California data base), and is unlikely to withstand the scrutiny of peer review.

Response. The Agency proposes to use the PNET II model, a leaf-level model based on the response of a biochemical process (net photosynthesis) to ozone. There are notable concerns regarding the use of PNET II, and some are serious enough that the Agency needs to justify its

[1] See Appendix A for a list of such citations.

selection. The model's shortcomings must be addressed in order to assure a platform for future analyses that is state-of-the-art and flexible enough to capture various forms of air pollutants. The most significant concerns are: 1) the over-inflation of ozone effects on tree growth; 2) the reductionist approach; 3) the difficulties in our ability to scale up to forests outside of the Northeast and to consider other pollution (e.g., N) and climate (e.g., carbon dioxide, temperature) stresses; 4) possible limitations in the ability to address stand-level interactions; and 5) the ability to link to a GIS-based methodology.

We advise the Agency in planning for the next Prospective Studies to seek assistance from the EPA Corvallis Laboratory. This group, along with scientists at Boyce Thompson Institute at Cornell University, is conducting an extensive analysis of the response of forest ecosystems to ozone pollution at regional and national scales.

Issue 2.5. The criteria for selection of case study estuaries and the treatment of case study results in the analysis of the impacts of nitrogen deposition

Response. The methodology for this analysis is state of the art, using a Geographic Information Systems (GIS)-based approach. This methodology allows for refinements well into the future, including changes in the retention properties of systems for N, inclusion of other sites and modifications in the economic analysis. We commend the Agency in the selection of this methodology.

The Agency is proposing to aggressively pursue this approach using three estuaries from the East Coast. We support conducting these examples since they can be used to illustrate the potential relative significance of these types of benefits versus other quantified benefits. While it would be beneficial to highlight the amount of estuary resources that may receive benefits from reduced N loadings, vis-a-vis those for which the sample computations are conducted, we do not think the analysis for the three examples could be readily transferred to other estuaries at this time. We believe this effort would be better deferred to a subsequent Prospective Study where more attention can be given to assembling data for new analyses for carefully selected cases that are more representative of the range of United States estuarine systems in general and to the transfer from case studies to other sites.

A major concern is the limitation of these case studies to the East Coast estuaries. Freshwater systems need to be included (especially the Great Lakes), as well as comparable ecosystems on the West Coast. Freshwater ecosystems will require the same methodology but a different analysis in terms of the ecology as well as the economic assessment. The most notable case for the latter is high-elevation freshwater systems that are prized as pristine environments.

Issue: 2. 6. The rationale for considering the recreational fishing impacts of nitrogen deposition in a qualitative manner only.

Response. The ecological assessment appropriately expanded its conceptual focus.

However, the implementation continues to be significantly restricted by the lack of a good quantification of N deposition and its impacts. To be consistent with Section 812 of the CAAA, the current Prospective Study should identify where and how the assessment can practically be extended in the next iteration.

The next Prospective Study should benefit from quantifying more benefits in physical terms (e.g., emissions, exposures, impacts), even if monetization is not possible. Such additional physical quantification will assist readers in better assessing the potential significance of non-monetized benefits and, ultimately, will support development of the parameter values that will permit eventual monetization.

Additional Recommendations on the Ecological Assessment. The section on "Future Research Needs" should be revised to take account of the following:

(a) The section should identify research needs in ecology, especially to better characterize the service flows that are affected by air pollutants and to identify those functions and services of ecosystems most at risk and where the largest potential economic benefits might be found.

(b) The discussion of ecosystem integrity should acknowledge the problematic character of this term as a basis for assessing the effects of air pollutants on ecosystem functions and services.

(c) The Agency should reconsider whether the issues raised concerning discounting and financial market options pricing techniques are of significance for the assessment of ecological benefits.

(d) The Agency should develop objective criteria for selecting “representative” estuaries to be used as case studies for evaluation.

Charge Question 3. In response to the emergence of new information and analysis, EPA has recently re-evaluated the literature and developed a new approach to estimating reductions in mortality resulting from decreased ozone concentration. EPA proposes to use a Monte-Carlo based meta-analysis of the literature relating ozone concentrations and mortality, and requests comment on the following four issues:

Issue 3.1. Soundness of Approach. Reviewers should address the suitability of the study authors’ meta-analysis technique, and evaluate the method against other possible meta-analysis techniques.

Response. The Subcommittee agrees that meta-analysis, after stratifying for important coviariates (e.g., per capita gross domestic product, see response to Issue 3.7. below), is a suitable statistical method to combine results from the pre-selected studies for the purpose of obtaining an estimate of the ozone-mortality relationship. The Subcommittee does not agree that a careful examination of the statistical results of previous studies is likely to add valuable information on the mortality and other health effects of ozone. Since many of the studies used the same data bases and arrived at divergent conclusions, there seems to be no alternative to either having EPA gather the data and perform its own analysis or to ask the various authors to use their data sets to run EPA specified models.

Issue 3.2. Study Selection Criteria. Reviewers should consider the appropriateness and comprehensiveness of the nine study selection criteria used in the meta-analysis, and/or suggest alternative or additional criteria where appropriate. In particular, EPA requests comments on the use of European studies to characterize US concentration-response (C-R) functions.

Response: The Subcommittee suggests, as an additional criterion for selection of studies to include in the meta-analysis, that studies be grouped by countries similar with respect to per capita gross domestic product. That is, studies conducted in the more developed and industrialized countries (United States, United Kingdom, western Europe, Canada, and Australia) could be analyzed separately from those in developing countries. The rationale for this stratification is the fact that the underlying mortality experience of the developed and developing countries differs by age, major cause groupings, and overall age-adjusted rates. Thus, the ozone-mortality association may differ among these strata as well. In effect, this criterion would eliminate results from the Latin American countries from the current Prospective Study, since there are too few studies at this time from these countries to allow a stratum-specific analysis.

The report does not explicitly state the reason for excluding some specific studies from the meta-analysis. Twenty studies cited in Table 2 are reported to have measures of particulate matter (PM) and ozone, yet only ten of these were included in the meta-analysis. The Subcommittee suggests that the authors indicate which of the exclusion criteria were applied to each of the ten excluded studies.

Of the ten selected studies, regression coefficients from three studies are based on daily 24-hour average ozone concentrations, while coefficients from the other seven use daily one-hour maximum concentrations. As the authors recognize, these two sets of coefficients are not strictly comparable. To investigate the use of ozone measures, it might be possible to obtain the raw ozone data for at least the two Philadelphia studies. This would allow an analysis of the mortality relationship with daily one-hour maximum values that could be compared to the published relationship to the 24-hour average ozone. We recognize that this analysis might not be feasible within the time constraints associated with this Prospective Study, but this could be very important to establishing the credibility of the meta-analysis.

Because the Philadelphia studies are heavily weighted in the meta-analysis by virtue of the long period of observation, the Subcommittee also suggests investigating more recent studies of air quality to establish associations for the averaging time appropriate for PM, ozone, and other related pollutants, and the air pollution-mortality associations in that city. Daily fine and coarse PM and ozone data are available for a three-year period in the 1990s, and it is possible that other investigators are using these data to analyze multi-pollutant relationships with mortality, or to analyze air quality in the Philadelphia region.

Some otherwise well conducted and potentially informative studies were excluded because they did not use an entire year of ozone data (thus failing to meet one of the criteria for selection). The Subcommittee believes it is not necessary to have ozone data for the entire year. The Subcommittee recommends that the authors of the meta-analysis obtain the summer-season ozone-mortality regression coefficients for these studies and evaluate whether they are suitable for incorporation in the meta-analysis as a separate data analysis that focuses only on the summer.

Issue 3.3. Treatment of Uncertainty. Reviewers should specifically address any concerns or problems associated with the authors' treatment of uncertainty surrounding reported ozone regression coefficients.

Response. As noted by the authors, although the meta-analysis does not characterize the uncertainty associated with the estimates of ozone concentrations in the individual studies, it does take into account the variability of the ozone-mortality coefficients within and between studies. To reduce uncertainty, additional studies that incorporate data from longer periods of time and from cities with large population bases are needed, however, this may not be available for the current Prospective Study. It is still uncertain whether the ozone-mortality coefficient varies by region of country and by season of year, and these uncertainties can only be resolved with newer data that will be useful for future Prospective Studies. Upon review, these studies should also be weighted by the standard error of the estimate or the square root of the population size.

Issue 3.4. Interpretation of Results. EPA seeks guidance on interpreting the meta-analysis results relative to the Pope PM study; i.e., the appropriateness of using these results to estimate the share of mortality attributable to ozone exposure, versus mortality incremental to the results of the Pope et al. study.

Response. The question of whether this meta-analysis can be interpreted to provide an estimate of the share of the air pollution-induced mortality attributable to ozone exposure has not been adequately addressed at this point in time. The Subcommittee is not convinced that the analysis has demonstrated an independent mortality effect of ozone in the presence of co-pollutants. In part, this lack of conviction is due to the fact that the driving force behind the final regression coefficient, as shown in Figure 6 of the Post et al. manuscript, is the large Philadelphia data set, in which substantial co-linearities existed among the several pollutants included in the model. The lack of demonstration of an independent ozone effect may also be attributable to the relatively small effect of ozone on daily mortality. These uncertainties require additional studies in cities where there is less co-linearity between ozone and co-pollutants, or studies over longer periods of time when the probability of a temporal separation of ozone from other pollutants is greater. The Subcommittee suggests that this lack of a convincing independent mortality effect of ozone be discussed in the report.

An alternative explanation is that ozone is acting as a weak surrogate of fine particle mass. Of the 10 studies considered in the meta-analysis, four showed significant ozone effects when a measure of PM was added to the analysis. Only 1 of those 4 studies (Ito and Thurston) used PM10 as a PM measure. The other 3 studies used either total suspended particulates or Black Smoke as PM measures. These two measures are poor surrogates for fine particle mass, and it is reasonable to expect that ozone may be as good a surrogate, if not a better one in these three studies. In contrast, of the six studies included in the meta-analysis that did not show a statistically significant effect, all but one (Borja-Aburto et al. 1997) used good surrogates of fine particle mass, either PM10 or light scattering coefficient. In these studies it is reasonable to expect that the PM measure captured the mortality effect better than did ozone.

The co-linearity that is a problem with decoupling PM and ozone can be due to the fact that during the high ozone season, summer, the photochemical reaction leading to ozone formation also leads to the production of fine particle mass in both the organic and inorganic fractions. Thus, the covariation between ozone and PM may be difficult to remove during periods of high pollution.

Charge Question 4. HEES encouraged EPA to evaluate a wide range of threshold assumptions in the PM mortality analysis. In response to HEES' comments on this issue, EPA performed a sensitivity analysis of thresholds below and above the annual $PM_{2.5}$ standard of $15 \mu g/m^3$. EPA requests guidance from the HEES on the following points:

Issue 4.1. Clarification of the HEES analytic basis for rejecting use of the lowest observed effects level as estimated in the underlying health effects literature;

Response. Charge Question 4.1. relates to treating "the lowest observed effects level" from the epidemiological literature as an effects threshold. The implication is that the same literature identifies a lower "no observed effects" level and that a judgment could be made that a level somewhere between the lowest effects level and a lower no-effects level could be selected as a threshold. The Subcommittee does not believe that any of the reviewed concentration-response functions (C-R) functions have data adequate for such a selection based on established scientific criteria. The lowest effects levels of statistical significance generally seem to be determined more by the size of the population and the numbers of observations made, rather than by the nature of the analyses.

Issue 4.2. Clarification of the analytic basis for any threshold greater than the $15 \mu g/m^3$ level.

Response. Our recommendation to assume a threshold of $15 \mu g/m^3$ was directed solely at completing a sensitivity analysis. There is no scientific basis for $15 \mu g/m^3$ as an effects threshold, if threshold is defined as an absence of observable effects. This was acknowledged by the Administrator when the standard was promulgated. Thus, there cannot be an analytic basis for a threshold level above $15 \mu g/m^3$, either. This point seems to be derived from a misinterpretation of information presented in our February, 1999 HEES Advisory (EPA-SAB-Council-ADV-99-005). Such an misinterpretation may have been possible, but it is an unreasonable interpretation based upon the science.

Issue 4.3. Suggestions for an analytically defensible approach to developing concentration-response functions (C-R) that correctly adjust for the threshold assumption. In particular, EPA requests advice on whether introducing a threshold implies changes to the functional form and slope of the C-R function that is derived from the underlying studies.

Response. Charge Question 4.3 seeks guidance on the use of adjusted C-R functions for responses above any threshold level that has been arbitrarily selected. If the C-R function is not linear, then the best fit to the data above the threshold level will differ from the function that fits all of the data. Thus, when the data are forced into a threshold model, a recalculated C-R function for the data above the threshold would be appropriate, but this may introduce uncertainties since there is no scientific justification for changing the functional form or the slope. Logically one would assume that there is no benefit in reducing the concentration below a threshold, if a threshold existed.

Charge Question 5: In response to HEES suggestions, EPA plans to: incorporate the revised Pope data; reduce PM-related neonatal mortality to an illustrative calculation; incorporate the most current research on carbon monoxide-related health effects, chronic bronchitis incidence, and ozone-related emergency room visits for asthma; develop a summary table of uncertainties; and present non-monetized health benefit results relative to national incidence rates. EPA requests HEES review these changes in the review material submitted to ensure they adequately reflect concerns expressed in previous HEES meetings.

Issue 5.1. Incorporation of the revised Pope data.

Response. The HEES notes that the Pope et. al. study[2] reported the median as the estimator of central tendency instead of the mean. It would be appropriate for future analyses to analyze these data in terms of the mean. The Subcommittee recommends that the Pope data set be used to estimate the mortality coefficient for PM because this data set provides a basis for estimating the cumulative mortality impact, whereas estimates based on daily mortality studies may fail to provide a satisfactory basis for anything more than estimating a short-term mortality effect. Since the mean pollutant concentration is the more common measure of central tendency used in other health studies, there appears to be no justification for using the median PM concentration when applying the Pope data to derive a national estimate. This error should be corrected in the final analyses. A notation about this issue should be made in the current report and the mean must be employed for ambient concentrations and exposure-response functions in the future.

The Six-Cities study was not used in this Prospective Study. The study had better monitoring with less measurement error than did most other studies (which may partially explain why estimates of PM-related mortality are greater than those estimated by Pope). Future studies

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[2] Pope, C.A. III; Thun, M.J.Namboodiri, M.; Dockery, D.W.; Evans, J.S.; Speizer, F.E., and Heath, C.W., Jr. Particulate Air Pollution is a Predictor of Mortality in a Prospective Study of U.S. Adults. Am. J. Respir. Care Med., Vol. 151, March 1995, pp.669-674.

need to evaluate the degree to which better exposure assessments will improve the precision of health outcome estimates. The Pope et al. 1995 study only included PM. The use of the PM-only metric may, therefore, subsume some fraction of the ozone-associated mortality within the PM-associated mortality. The degree to which this occurs is likely to be small (as per the ozone meta-analysis). Because no other ozone-mortality component is currently planned for inclusion in the current Prospective Study, this should not be a source of double counting.

Issue 5.2. Reduce PM-related neonatal mortality to an illustrative calculation.

Response. The various studies of neonatal mortality associated with criteria pollutant concentrations do not provide a sufficient basis for quantifying results at this time. Even though there were additional studies published since the previous HEES recommendation, the studies were of marginal relevance to United States mortality issues because of differences in populations, socioeconomic factors, and pollutant concentrations. However, neonatal mortality may be an important issue. Experience from the London 1952 episode demonstrated that those <1 and >45 years of age were at greatest risk and were the groups exhibiting excess mortality. However, it should be noted that the levels of PM and sulphur dioxide were about two orders of magnitude greater than that observed in the US in the (1999) study. The Pope et. al. study is only applied to individuals >30 years of age, hence the issue of neonatal mortality needs to be revisited in the future as new evidence accumulates.

Issue 5.3. Incorporate the most current research on carbon monoxide-related health effects.

Response. This issue can be rephrased as: Should hospitalization analyses rely solely on the Burnett et al. 1999 study that links carbon monoxide and other pollutants or should a broader set of hospital admission studies be used? The HEES suggests that the PM estimates in the Burnett study are indirect measures of PM2.5 and coarse particles and, therefore, the study is not strictly controlled for fine or coarse particle mass. For this reason the HEES recommends including a select, but larger, set of studies for carbon monoxide-related health effects for future analyses.

Issue 5.4. Incorporate the most recent studies on chronic bronchitis incidence.

Response. The HEES concurs with the use of the most recent data on chronic bronchitis incidence, but recommends that the methods for estimation of incidence from reported prevalence data be more thoroughly evaluated. The extrapolation of the Abbey et al. study incidence rates to other populations may be problematic because of the low percentage of smokers in that study population.

Issue 5.5. Ozone-related emergency room (ER) visits for asthma.

Response. The HEES concurs that ER visits should be included as an endpoint and acknowledges the problem of estimating the incidence of asthma-related ER visits.

Issue 5.6. Develop a summary table of uncertainties.

Response. The HEES concurs and recommends that the summary table format used in the retrospective study, *The Benefits and Costs of the Clean Air Act; 1970 to 1990 (October 1997)* be applied to the Prospective Study.

Issue 5.7. Present non-monetized results in terms of the national incidence rates.

Response. The HEES concurs with the presentation of a given pollutant and its associated effect as a percentage of the national incidence rate for that effect.

Charge Question 6: In response to HEES recommendations, EPA is developing a qualitative characterization of regional variation in C-R functions. EPA requests guidance on specific studies that document the extent of regional variation.

Response. Studies of similar endpoints in multiple geographic regions have reported substantial variation among C-R functions across regions. This variation is likely to result from differences in regional atmospheric conditions and emissions and/or demographic characteristics (such as income) and not result solely from statistical uncertainty. At this point, however, the health-effects literature does not provide an adequate basis to support detailed rigorous analysis of reported regional variations. Consequently, it is premature to undertake quantitative assessment of regional variations, pending the outcome of on-going studies likely to be completed within the next three to five years.

Charge Question 7.1. and 7.2. Regarding assessment of the benefits of reductions in air toxics, EPA requests guidance and clarification from the HEES as to how in-depth review of high-risk Hazardous Air Pollutants (HAPs) can be used to generate estimates of avoided health impacts due to reductions in HAP exposure, given the scarcity of HAP monitoring data and HEES significant concerns about the reliability of HAP concentration estimates generated by the ASPEN model. An initial plan for future HAP-related benefits assessment is being submitted along with this charge, and a briefing describing this plan more fully will be presented to the HEES at the April 20-21, 1999 review meeting. This plan describes the Agency's ongoing and future efforts related to HAP-related emissions inventory development, air quality modeling, exposure assessment, and risk assessment. EPA requests comment regarding the extent to which the HEES anticipates that these ongoing and planned efforts might increase the technical and scientific validity and reliability of subsequent quantitative estimates of HAP reduction benefits, especially with respect to the specific technical and scientific issues identified previously by the HEES.

Response. There are three major gaps in our scientific knowledge that prevent the Agency from carrying out a comprehensive assessment of the benefits of controlling emissions of hazardous air pollutants under the Clean Air Act Amendments of 1990. They are:

a) a lack of information on the exposures of populations at risk;

b) the need for power calculations to determine what is conceivably observable; and

c) the absence of risk characterizations for most HAPs that are based on the best estimates or most likely values for individual cancer risks and risk of other health effects, rather than on the upper-bound estimates of risks and on conservative extrapolation assumptions. HEES believes that while the conservative characterizations of individuals' risks may be appropriate for regulatory decision making, they should not be used in the Prospective Study since they are not consistent with the best estimates of risks used for criteria pollutants in the Assessment.

d) HEES believes that both the exposure assessments and risk characterizations for HAPs are complex problems and that they might best be addressed by convening a group of relevant experts from both the Environmental Health Committee and the Integrated Human Exposure Committee of the SAB and other professionals to consider the strengths and weaknesses of our present knowledge and relevant models and to provide advice on how to apply this to the Prospective Studies in future years. This group should specifically address how to provide best estimates of cancer risks from the available risk assessment data, and whether ASPEN can be used to reliably predict exposures for populations at risk or whether another more sophisticated model needs to be employed to predict total exposure. The April presentation did not address the reliability of ASPEN, and screening analyses on some selected HAPs compounds still need to be performed.

We recommend that in the meantime the Agency select a small number of HAPs (perhaps 1 - 3), including benzene, to do a screening analysis based on existing monitoring data and the best available data on individual risks. This screening analysis would be based on the steps outlined in our February 1999 HEES Advisory (EPA-SAB-Council-ADV-99-005) pp. 10-11.

In addition, the Subcommittee recommends that the Agency conduct a HAP case study in which the endpoints for concern are largely ecological ones. We recommend that the Agency advance a consistent approach and acknowledge the significance of ecological effects for air toxics as it has for criteria pollutants. We recommend that mercury be chosen as the HAP of interest for this purpose.

Conclusion

We thank the Agency for the opportunity to be of service in review of the building blocks that will lead to the forthcoming Prospective Study and to the review of the draft Study itself. We look forward to the response to this Advisory from the Assistant Administrator of the Office of Air and Radiation.

Sincerely,

Dr. Maureen L. Cropper, Chair
Advisory Council on Clean Air
Compliance Analysis

Dr. Paul Lioy, Chair
Health and Environmental Effects
Subcommittee
Advisory Council on Clean Air
Compliance Analysis

APPENDIX A
Selected References Related to Nitrogen Deposition to Continental Landscape

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GLOSSARY OF TERMS AND ACRONYMS

ADV	Advisory
AQMS	Air Quality Models Subcommittee (of the Council)
CAAA	Clean Air Act Amendments
C-R	Concentration-Response
EPA	U.S. Environmental Protection Agency (U.S. EPA)
GIS	Geographic Information System
HAP	Hazardous Air Pollutant
HEES	Health and Ecological Effects Subcommittee (of the Council)
LTR	Letter Report
N	Nitrogen
PM	Particulate Matter
$PM_{2.5}$	Particulate Matter (2.5 microns in diameter)
PM10	Particulate Matter (10 microns in diameter)