energy API

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VIA ELECTRONIC MAIL:
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Economist and Designated Federal Officer Clean Air Scientific Advisory Committee (CASAC)
Environmental Economics Advisory Committee (EEAC) Science Advisory Board Staff Office (1400F)
Environmental Protection Agency
1200 Pennsylvania Ave.,
NW Washington D.C. 20460

RE: Comments on the Draft 2008 EPA Report Guidelines for Preparing Economic Analyses, September 12, 2008

Dear Dr. Stallworth:

API appreciates the opportunity to comment on the above cited EPA draft report, which addresses issues associated with past and future risk and economic analyses conducted for regulatory purposes. API is a national trade association with nearly 400 member companies involved in all aspects of the oil and natural gas industry. Each year, API's members' facilities are subject to dozens of new regulations addressing environmental, economic, and security issues at a cost of billions of dollars. Therefore, EPA's draft report and guidelines have a direct and substantial impact on our members.

Our enclosed comments emphasize the following points:

- API recommends, per OMB *Circular A-4,* that a real discount rate of 7 percent be employed in economic analyses as the default discount rate (base case) in cases where the regulation falls primarily on the allocation of capital.

- The Agency recommends the use of discount factors estimated by Newell and Pizer (2003) for intergenerational policies having a long time horizon (50+ years). Given that the Agency does not provide the specific rates recommended, but rather only references a table in the Newell and Pizer (2003) publication, the above recommendation for intergenerational discount rates is premature and should be removed from the document until this information becomes available for public comment.

- API questions the validity of EPA's assumption that the growth rate is declining systematically over time, which corresponds to a declining discount rate, as assumed in many climate models.

- API recommends that EPA use the value of life year lost (VOLY) approach as the preferred method of calculating the economic benefits of changes in mortality. At a minimum, EPA should use the VOLY approach in conjunction with value of statistical life (VSL), as recommended in the OMB *Circular A-4* guidelines.

- EPA should take a more rigorous approach in the draft Guidelines to ensure uncertainties are accurately characterized in economic analyses and that the reports of the analyses communicate clearly the overall uncertainties. Uncertainties in various stages of economic analysis are compounded in the final analytic product. Causes of uncertainties include lack of data or use of outdated data, use of worst-case assumptions for input parameters, use of outdated, flawed or unvalidated models, and uncertainties within modeling algorithms themselves. Probabilistic uncertainty analysis would be one way to better quantify these uncertainties. API strongly recommends rigorous implementation of OMB and federal agency information quality guidelines for economic, risk assessment, cost-benefit, and cost-effectiveness analyses.

- API supports the OMB requirement (per OMB *Circular A-4*) for a formal probability analysis of benefits and costs for rules with economic impacts exceeding $1 billion per year. API recommends that agencies promulgating regulations with impacts of $100 million or more per year conduct a formal uncertainty analysis that covers all key model parameters and addresses both benefits and costs. This $100 million per year threshold is consistent with Executive Order 12866, requiring OMB review of significant rulemakings.

- A major notable weakness of the EPA Guidelines is the failure to mention the need to comply with the OMB and EPA Information Quality Guidelines. The draft Guidelines should be revised to incorporate EPA's requirements to fulfill OMB's and the Agency's Information Quality Guidelines.

API cites numerous documents in the enclosed comments. While not attached to this comment package, they are all easily available through regulatory dockets, or by request to API. Please contact me (202-682-8340 or feldman@api.org) should you wish to request any of the cited documents, or if you have any questions regarding these comments.

Sincerely,

Enclosure

API Comments on
Guidelines for Preparing Economic Analyses

National Center for Environmental Economics
Office of Policy Economics and Innovation
U.S. Environmental Protection Agency
Draft September 12, 2008 Report

EXECUTIVE SUMMARY:

API appreciates the opportunity to comment on the U.S. Environmental Protection Agency's ("EPA" or "Agency") draft *Guidelines for Preparing Economic Analyses* ("Guidelines"). API commends EPA for developing guidelines to promote greater transparency and consistency in the conduct and reporting of economic analyses at the Agency. Development and adherence to guidelines facilitate and improve efforts such as the Office of Management and Budget's (OMB) recent 2008 annual report to Congress on the benefits and costs of federal regulations.[1] Transparent, clear guidance is critical to combining and comparing benefit-cost analyses of regulations across federal agencies.

API strongly supports the Agency's goal to develop additional guidance related to cost-effectiveness analysis and uncertainty analysis. As outlined in OMB's *Circular A-4*[2], "a major rulemaking should be supported by both types of analysis [benefit-cost analysis and cost-effectiveness analysis] whenever possible" (OMB *Circular A-4*, page 9). Additionally, the recent National Research Council's report by the Committee on Improving Risk Assessment Approaches, a committee commissioned by EPA, stressed the need for improved methods to characterize and communicate existing uncertainties in all key computation steps of risk assessment.[3] The pending uncertainty analysis guidelines should include key OMB recommendations regarding treatment of uncertainty, such as for rules with annual economic impacts of $1 billion or more: "when benefit and cost estimates are uncertain...you should report benefit and cost estimates (include benefits of risk reductions) that reflect the full probability distribution of potential consequences" (OMB *Circular A-4*, page 18). A good illustration of quantitative uncertainty analysis methods is the probabilistic uncertainty analysis conducted by Jaffe and Stavins (2004) relating to EPA's Nonroad Diesel Rule. Given the importance of the pending guidelines on cost-effectiveness analysis and uncertainty analysis, the Agency should make the draft guidelines available for public comment when they become available.

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[1] Office of Management and Budget, Office of Information and Regulatory Affairs. "2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities." http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/2008_cb_final.pdf.

[2] Office of Management and Budget, Office of Information and Regulatory Affairs. (September 2003). Circular A-4, Regulatory Analysis. http://www.whitehouse.gov/omb/assets/omb/circulars/a004/a-4.pdf.

[3] National Research Council (NRC) of the National Academies. (2008). Science and Decisions: Advancing Risk Assessment. Committee on Improving Risk Analysis Approaches by the U.S. EPA, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. Prepublication copy, November 2008.

API highlights its key comments below, with additional detail provided in the main body of the document.

API comments emphasize the following points:

- API recommends, per OMB *Circular A-4,* that a real discount rate of 7 percent be employed in economic analyses as the default discount rate (base case) in cases where the regulation falls primarily on the allocation of capital.

- The Agency recommends the use of discount factors estimated by Newell and Pizer (2003) for intergenerational policies having a long time horizon (50+ years). Given that the Agency does not provide the specific rates recommended, but rather only references a table in the Newell and Pizer (2003) publication, the above recommendation for intergenerational discount rates is premature and should be removed from the document until this information becomes available for public comment.

- API questions the validity of EPA's assumption that the growth rate is declining systematically over time, which corresponds to a declining discount rate, as assumed in many climate models.

- API recommends that EPA use the value of life year lost (VOLY) approach as the preferred method of calculating the economic benefits of changes in mortality. At a minimum, EPA should use the VOLY approach in conjunction with value of statistical life (VSL), as recommended in the OMB *Circular A-4* guidelines.

- EPA should take a more rigorous approach in the draft Guidelines to ensure uncertainties are accurately characterized in economic analyses and that the reports of the analyses communicate clearly the overall uncertainties. Uncertainties in various stages of economic analysis are compounded in the final analytic product. Causes of uncertainties include lack of data or use of outdated data, use of worst-case assumptions for input parameters, use of outdated, flawed or unvalidated models, and uncertainties within modeling algorithms themselves. Probabilistic uncertainty analysis would be one way to better quantify these uncertainties. API strongly recommends rigorous implementation of OMB and federal agency information quality guidelines for economic, risk assessment, cost-benefit, and cost-effectiveness analyses.

- API supports the OMB requirement (per OMB *Circular A-4*) for a formal probability analysis of benefits and costs for rules with economic impacts exceeding $1 billion per year. API recommends that agencies promulgating regulations with impacts of $100 million or more per year conduct a formal uncertainty analysis that covers all key model parameters and addresses both benefits and costs. This $100 million per year threshold is consistent with Executive Order 12866, requiring OMB review of significant rulemakings.

- A major notable weakness of the EPA Guidelines is the failure to mention the need to comply with the OMB and EPA Information Quality Guidelines. The draft Guidelines

should be revised to incorporate EPA's requirements to fulfill OMB's and the Agency's Information Quality Guidelines.

DETAILED COMMENTS ON EPA DRAFT REPORT GUIDELINES FOR PREPARING ECONOMIC ANALYSES, SEPTEMBER 12, 2008:

Discounting Future Benefits and Costs [Chapter 6]

EPA states "The social opportunity cost of capital represents a situation where investment is crowded out dollar-for-dollar by the cost of environmental policies. This is an unlikely outcome, but can be useful for sensitivity analysis and special cases" (lines 25 – 27, pages 6-13). Such statements are used by EPA to justify use of a 3% or lower discount rate in benefit-cost analysis of environmental regulations.

EPA establishes the basis for this argument by characterizing EPA environmental regulations as taxpayer-funded public projects and poses the question whether or not these public projects distort capital markets, interest rates, etc. It is argued that typical EPA regulations are relatively small compared to the overall size of the U.S. capital market, and therefore, given the size and the "open economy" assumption of the U.S. capital market, crowding out of private investment due to EPA regulations, if it exists at all, is minimal.

This argument ignores the fact that many (if not most) of EPA regulations are not accurately characterized as "public projects" but rather are direct regulations on private industry. There is no question that EPA environmental regulations on the oil and gas industry have diverted capital from higher-return investments to investments made to comply with environmental regulations. This effect also likely holds for many if not most of the environmental regulations on U.S. industry.

This diversion of private capital to lower-return investments results in a lower overall return to capital in the industry, lower future productivity and growth, and ultimately lower returns to shareholders. This outcome is at odds with the EPA conclusion above that crowding out of private capital is an unlikely outcome of environmental regulations.

API therefore strongly recommends, per OMB *Circular A-4*, that a real discount rate of 7 percent be employed as the default rate (base case) in cases where the regulation falls primarily on the allocation of capital. This rate is justified, as it is a reasonable estimate of return to all private capital in the U.S. economy inclusive of corporate, real estate, small business, etc. However, it may be possible to discern with greater precision where the principal displacement of capital due to the regulation occurs. If, for example, it can be determined that the regulation displaces principally corporate capital, a higher discount rate could be justified, depending on the sector, as pointed out in OMB *Circular A-4*.

With respect to regulations expected to impact significantly across generations, the Agency suggests that analysts also use the schedule of discount factors estimated by Newell and Pizer[4] for policies having a long time horizon (50+ years) and where net benefits vary substantially over time. The Agency does not provide the specific rates recommended, but rather only references a table in the Newell and Pizer publication. Additionally, the Newell and Pizer study appears to be single study for which few details are provided regarding methods and/or data. The Agency states that it will be providing "an empirical supplement that provides specific rates based on this approach" (lines 32-33, pages 6-22). Thus, until this supplement becomes available for public comment, the above recommendation for intergenerational discount rates is premature and should be removed from the document.

Finally, EPA states: "In particular, one may assume that the growth rate is declining systematically over time (perhaps to reflect some physical resource limits), which will lead to a declining discount rate. This is the approach taken in some models of climate change" (lines 5 – 7, pages 6-20). It is not at all clear that the assumption of a declining growth rate (due to physical resource limits) is valid. This assumption ignores technological innovation that can result in higher future growth rates and hence higher discount rates in the future as resource constraints become less binding due to technological advancement.

Analyzing Benefits [Chapter 7]

In section 7.2.1.1: *Human Health Improvements, Mortality*, EPA states: "Some EPA policies will lead to decreases in the risk of premature mortality due to potentially fatal health conditions, such as cancers. In considering the impact of environmental policy on mortality, it is important to remember that environmental polices do not assure that particular individuals will not prematurely die of environmental causes; rather, they lead to small changes in the probability of death for many people" (lines 18 – 22, pages 7-6).

The concept that environmental policies can reduce the "probability of death" for any individual or group of people is not accurate because this probability is fixed at 1.0, (i.e., environmental policies can never "save" a life, but rather extend the duration of a lifetime). As such, the relevant question for environmental policy is how many years of a life can one "save." The Agency's conceptual error has led to a singular focus on use of the Value of Statistical Life (VSL) for economic analysis for all mortality events, even for events that, *if* they are causal, are believed to reduce life expectancy by at most a few months. An example is acute mortality estimates derived from time-series epidemiology studies.

The exclusive use of VSL, combined with use of a fixed high-end VSL value (discussed further below) and high end concentration response functions, has resulted in the over-estimation of the

[4] Newell, R.G. and William P.A. (2003). "Discounting the Distant Future: How Much Do Uncertain Rates Increase Valuations?" JEEM. Vol. 46, No. 1, pp. 52-71.

economic value of changes in air pollution. In fact, the recent conclusion by OMB[5] that regulations in general are "cost effective" hinges largely on the accuracy of what in our view are exaggerated estimates of the economic value of reductions in mortality associated with incremental decreases in air pollution. Because these estimates are based on observational epidemiology studies, which rely on group rather than individual-level data, the results can never be verified with actual data, as per for example, interventions that result in decreased traffic mortalities. This is critical from a risk management and accountability perspective.

As pointed out by Rabl et al. (2006)[6] and others, there is no such thing as "extra deaths," "reduced probability of death," or "statistical lives saved." Rather, air pollution *could potentially* reduce one's life expectancy or cause an average loss of life expectancy across a population. Therefore, Rabl recommends expressing air pollution mortality in terms of Loss of Life Expectancy (LLE) changes. This framework automatically takes into account the constraint that everybody dies exactly once, regardless of their exposure, or lack thereof, to air pollution. The LLE approach was recognized by the European Union (EU) as providing a more accurate and meaningful metric to quantify potential chronic effects of air pollution. The LLE, or more specifically, the value of life year lost (VOLY) approach was used in conjunction with the VSL approach to evaluate various policy options for reducing PM air pollution under the EU Clean Air for Europe program (AEA, 2005).[7] In the case of ozone, which was only presumed to cause acute mortality based on time series studies, the economic evaluation used only the VOLY approach. Moreover, the above approach of using both VSL and VOLY in estimating benefits of air pollution reductions is consistent with OMB *Circular A-4* recommendations.

Rabl et al. (2003)[8] further explained the concerns with estimating the number of premature deaths due to air pollution as not meaningful.

- First, it makes little sense to add the number of deaths independently due to different contributing causes, such as air pollution, smoking, or lack of exercise, because doing so could result in a number far in excess of total mortality. When individual air pollutants are considered without adequately adjusting for other pollutants, double counting of deaths in the analysis may result.
- Second, the number of deaths fails to take into account the magnitude of the loss of life expectancy per death, which is very different between, for example, air pollution deaths

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[5] Office of Management and Budget, Office of Information and Regulatory Affairs. "2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities."
http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/2008_cb_final.pdf

[6] Rabl, A. (2006). "Analysis of Air Pollution Mortality in Terms of Life Expectancy Changes: Relation between Time Series, Intervention, and Cohort Studies." Environmental Health, a Global Access Science Source, No. 5.

[7] AEA (2005). Methodology for the Cost-Benefit Analysis for CAFÉ. Vol. 2: Health Impact Assessment. AEA Technology Environment: UK.

[8] Rabl, A. (2003). "Interpretation of Air Pollution Mortality: Number of Deaths or Years of Life Lost?" J. Air Waste Management Assn. Vol. 53, No. 1, pp 41-50.

(typically occurring in older people) and traffic accidents (typically occurring in younger people).

- Third, by contrast to the primary causes of deaths (e.g., heart disease, cancer, etc.) with ecologic air pollution studies, it is not possible to accurately estimate the total number of premature deaths attributable to air pollution. The reason is that ecologic air pollution studies provide population-based "years of life lost," but not individual years of life lost per death. Therefore, it is not known if a few individuals lose a number of years of life or if many individuals lose only a few months.

API strongly recommends that EPA adopt the approach of calculating the economic benefits of air pollution that focus on mortality using the VOLY approach as the preferred method. At a minimum, EPA should use the VOLY approach in conjunction with VSL as recommended in OMB *Circular A-4*. This would provide risk managers a more robust range of economic benefit values to consider.

As part of the work to improve economic analysis of air pollution reductions under the EU CAFE program, a high-quality study was completed that provides reliable and credible VOLY estimates (NEEDS, 2006).[9] In contrast to the studies EPA has relied on to estimate the VSL, which focused on accidental deaths, the NEEDS study focused on VOLY lost by air pollution mortality, thereby avoiding significant benefit transfer-related concerns. API strongly recommends that EPA consider the VOLY estimates from the NEEDS research and consider developing similar estimates using a U.S. based survey.

In section 7.3 on valuation of ecological improvements, EPA has a very brief section devoted to the concept of avoiding double counting. It is not clear why this issue is not also addressed in the health section. API recommends expanding the section on double counting with a particular focus on addressing the issue of double counting of health benefits, which is a very serious problem in the risk assessment of NAAQS pollutants. The health endpoints EPA monetizes in NAAQS-style risk assessments are very non specific in nature (e.g., cardiopulmonary or respiratory mortality or morbidity). EPA now alleges nearly all NAAQS pollutants potentially cause mortality and morbidity. The studies EPA uses to estimate the occurrence of these events are observational air pollution studies. These studies examine highly correlated air pollutants using a group exposure metric (ambient monitors); complete disentangling of the effects of multiple air pollutants is not possible in these studies. EPA routinely uses single-pollutant model results in their risk assessments; this results in massive double, triple, and quadruple counting of mortality and morbidity risks.

Multiple counting of benefits has also resulted from EPA using chronic PM mortality reductions in multiple overlapping regulatory initiatives. For example, EPA calculated the benefits of reducing PM to meet the 2006 PM NAAQS as part of the RIA for this rule. However, EPA also monetized

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[9] NEEDS. (2006). "Final Report on the Monetary Valuation of Mortality and Morbidity Risks from Air Pollution." New Energy Externalities Developments for Sustainability. Project No: 502687. EU Sixth Framework Programme.

chronic PM reductions as part of the ozone RIA, and in their analysis of benefits of the Nonroad Diesel Rule, the Mobile Source Air Toxics Rule, the Clean Air Interstate Rule, the IMO initiative to reduce ship emissions, and numerous other regulatory initiatives. API strongly recommends that EPA addresses the issue of multiple counting of benefits across various regulatory initiatives with the goal of eliminating multiple counting of benefits.

The analysis should also account, to the extent possible, for countervailing impacts of regulations on life years saved. Compliance costs of federal environmental, health, and safety regulations exceed many billions of dollars annually. This translates into significant real costs to consumers that can displace other risk-reducing purchases, such as more comprehensive health insurance, safer motor vehicles, higher quality foodstuff, or membership in a health club (see, e.g., Hahn, Lutter and Viscusi, Do Federal Regulations Reduce Mortality, AEI-Brookings Joint Center for Regulatory Studies, 2000).

Finally, EPA is to be commended for highlighting the issue of integrating economics and risk assessment (page 7-18, text box 7.2). Particularly important points are the need to produce expected or central estimates of risk, rather than bounding estimates and in safety assessments; estimation of "cessation lag" associated with reductions in exposure; and characterizing the full uncertainty distribution associated with risk estimates.

Use of Stated Preference Methods [Chapter 7.4.2]

Chapter 7 also provides a good overview of revealed and stated preference methods. With regard to stated preference methods, section 7.4.2.3 provides considerations in evaluating the reliability and validity of results. Several validity tests are described (e.g., content validity, criterion validity), but there is no mention of other important tests such as examining how WTP changes with change in the commodity (i.e., does inclusion of more lakes cleaned up increase WTP and vice versa), sensitivity of results to bid price and general patterns in the data (e.g., do effects of demographics and debriefing responses conform to expectations).

Use of stated preference (SP) methods relies on hypothetical survey techniques that elicit from individuals how much they would be willing to pay, for example, to preserve a resource that they may never use or see. Such techniques can lead to misstatement of true preferences. Survey techniques are not based on any type of market price data nor are they derived from any utility maximizing or cost minimizing behavior. Hence, estimates derived from such survey techniques can be highly speculative, subject to manipulation, and highly uncertain, with the potential to significantly distort net benefit estimates. Given the methodological problems and limitations associated with SP techniques, API recommends that SP-derived estimates not be integrated into the Agency's benefit-cost estimates—rather it would be more appropriate to report such benefits separately. Also, critically important would be to quantify the uncertainty associated with SP-derived estimates. This would facilitate public review and guard against highly uncertain benefit estimates from driving the outcome of a benefit-cost analysis.

Presentation of Analysis and Results [Chapters 10.1 and 10.2]

API urges EPA to review OMB guidance for "Quantitative Analysis of Uncertainty" to ensure that uncertainty is handled appropriately in completing economic analyses and in the reporting of such analyses (68 Fed. Reg. 5523):

> *"Your [i.e., an agency's] estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Your analysis should not reflect any unstated or unsupported preferences, even for such worthy objectives as protecting public health or the environment. Unstated assumptions can affect the analysis in unsuspected ways, making it difficult for decision-makers to evaluate the true magnitude of the uncertainties involved"*

EPA should take a more rigorous approach in the draft Guidelines to ensure uncertainties are accurately characterized in economic analyses and that the reports of the analyses communicate clearly the overall uncertainties.

Furthermore, API supports the OMB requirement (per OMB *Circular A-4*) for a formal probability analysis of benefits and costs for rules with economic impacts exceeding $1 billion per year. API supports this principle as RIAs in the past have discounted or ignored altogether discussion of the uncertainties inherent in the benefit-cost estimates. However, API recommends that uncertainty analysis be required on the most critical parameters affecting net benefit estimates for *all* economically significant regulations. The degree of formality in the uncertainty analysis should be based on the impact of the proposed regulation. Agencies promulgating regulations with impacts of $100 million or more per year should be required to conduct a formal uncertainty analysis that covers all key model parameters and addresses both benefits and costs. This $100 million per year threshold is consistent with Executive Order 12866, requiring OMB review of significant rulemakings. For regulations with lesser impacts on the economy (e.g., $10 million to $100 million per year), the scope and detail of uncertainty analysis could be adjusted accordingly.

A pervasive feature in many of the steps of net benefit estimation is the lack of complete information. The choice of methods to characterize the risk is varied and will depend upon the quality and quantity of information available. For example, good information exists to characterize the risk of a U.S. citizen being killed in an automobile accident over the next year (about 24 in 100,000). It would be relatively more difficult to characterize the probability of harm from, for example, exposure to dioxins, and it would be extremely difficult to characterize the risk of cancer due to a new, untested drug with a chemical form unlike any existing drug (an example of true uncertainty). In cases where risk can be well-characterized, there is a well-accepted body of knowledge on how to incorporate risk into benefit-cost analysis. In such cases, formal treatment of uncertainty in benefit-cost analysis should pose no major methodological problems. In cases where true uncertainty prevails there is much less agreement on the best way to incorporate uncertainty into the analysis. In cases of true uncertainty, it will be much more difficult to formally incorporate

uncertainty into the analysis in a defensible way. API recommends that in cases of true uncertainty that EPA conduct additional research to better understand the risk before estimation of net benefits.

A prime example of a major rule put forward without sufficient understanding of the causal relationship among variables was EPA's standard for fine particulate matter ($PM_{2.5}$). As stated by the White House Office of Science and Technology Policy: "...the database for actual levels of $PM_{2.5}$ is also very poor, and only a handful of studies have actually studied $PM_{2.5}$ effects, per se. And current data do not support clear associations...so that causality for the observed mortality and morbidity effects cannot be established."[10] Studies (the so called Harvard Six Cities and American Cancer Society studies) cited by EPA as evidence in support of a $PM_{2.5}$ standard, as well as the reanalysis of those studies by the Health Effects Institute, failed to adequately assess the potential impacts of cofactors such as ozone or sulfur dioxide.[11] It is imperative that the direction and magnitude of causality among variables be sufficiently understood, (i.e., the uncertainty surrounding key parameters reduced), through additional research before an agency undertakes a benefit-cost analysis, let alone promulgates a major rule.

For rules not requiring a formal treatment of uncertainty, at a minimum a discussion of the principal sources of uncertainty in the benefit-cost analysis should be required. Better yet, sensitivity analyses reflecting major parameter uncertainties should be undertaken in net benefit estimation.

Formal treatment of uncertainty in benefit-cost analysis will provide policymakers with an additional dimension of information that they have not previously had, namely, an assessment of the confidence to be placed in the net benefits estimates. Such information would give policymakers confidence that the rules they are considering would indeed improve societal welfare, or whether additional data collection or analysis is necessary before rulemaking to resolve major uncertainties associated with the rule.

Reporting the Effects of Uncertainty on Results of Analysis [Chapter 10.2.2]

On page 10-5, EPA states "Delphic panels, or expert elicitation techniques, can help close knowledge gaps surrounding key relationships (see IEC, 2004)."

This statement implies that EPA plans to use the results of expert elicitation (EE) to address uncertainty in conducting risk assessments and to calculate the economic benefits of regulatory interventions, such as reductions in air pollution, given that the IEC report EPA references is for the concentration response relationship between $PM_{2.5}$ and mortality.

API strongly disagrees with the conclusion that EE in its current state of development can be used to address key issues of uncertainty in risk assessment. Therefore, we request that the above statement

[10] Memorandum from Rosina Bierbaum, Acting Associate Director at the White House Office of Science and Technology Policy, to Sally Katzen, OMB, entitled "OSTP Questions for EPA On Its Proposed Revisions to the Ozone and Particulate Matter Air Quality Standards, " November 15, 1996.
[11] See Jones and Lieberman, "The Ongoing Clean-Air Debate: The Science Behind EPA's Rule on Soot", 2001.

be deleted from the draft report. API also strongly recommends that the results of EE efforts should not be used in quantitative calculations of the benefits of environmental regulations. In particular, API recommends against using the results of the EE report on PM mortality in quantitative economic analysis.

The API position above is consistent with the recommendations of the National Research Council Committee on Improving Risk Assessment Approaches (CIRAA), a committee commissioned by EPA for the purpose of providing advice on improving risk assessment at EPA. In the chapter on uncertainty and variability, the CIRAA expresses serious concerns with both the methodology and use of EE. While OMB *Circular A-4* suggests that EE methods may enhance characterization of uncertainty, considerable experience with EE methods has been gained since the OMB document was written. Discussion of EE by the CIRAA was in the context of the recent EE report on PM, which the Committee used as an example to express their concerns. This text appears on pages 93-95 of the NRC report.

First, the CIRAA did not consider the information from the EPA PM EE report to be useful for weighing risk management options:

> "Expert elicitation can provide interesting and potentially valuable information, but some critical issues remain to be addressed. It is unclear precisely how EPA can use this information in its risk assessments. For example, in its regulatory impact analysis of the National Ambient Air quality Standard of PM2.5, EPA did not use the outputs of the expert elicitation to determine the confidence interval for the concentration-response function for uncertainty propagation but instead calculated alternate risk estimates corresponding to each individual expert's judgment with no weighting or comparing of judgments (EPA, 2006). It is unclear how that type of information can be used productively by a risk manager, inasmuch as it does not convey any sense of the likelihood of various values, although seeing the range of commonality of judgments of individual experts may be enlightening."

Second, the CIRAA also expressed concerns with the concept of combining or weighting the expert judgments to arrive at a central conclusion, given the various biases that exist in this kind of exercise:

> "Formally, combining the judgments can obscure the degree of their heterogeneity, and there are important meteorological debates on the merits of weighing expert opinions on the basis of their performance on calibration exercises (Evans et al, 1994; Budnitz et al, 1998). Two other problems are the need to combine incompatible judgments or models and the technical issue of training of the phenomenon being estimated (for example the risk of a particular disease at an environmental dose). Although methods have been developed to address various biases in expert elicitation, mischaracterization is still expected (NRC, 1996, Cullen and Small 2004)."

The CIRAA expressed serious reservations concerning the underlying cognitive tendencies that influence expert judgment and which cannot be accounted for. In our view, many of these

individual concerns apply directly to the case of the EPA PM EE effort, particularly those asterisked below:

> "Some findings about judgment in the face of uncertainty that can apply to experts are provided in box 4.3"
>
> > **availability:** the tendency to assign greater probability to commonly encountered or frequently mentioned events *
> >
> > **anchoring and adjustment:** the tendency to be over-influenced by the first information seen or provided in an initial problem formulation*
> >
> > **representativeness:** the tendency to judge an event by reference to another that in the eye of the expert resembles it even in the absence of relevant information
> >
> > **disqualification:** the tendency to ignore data or strongly discount evidence that contradicts strongly held convictions *
> >
> > **belief in law of small numbers**: the tendency of scientists to believe small samples form a population to be more susceptible than is justified *
> >
> > **overconfidence:** the tendency of experts to overestimate the probability that their answers are correct *
>
> "Other practical issues are the cost and time required for expert elicitation, *management of conflict of interest*, and the need for a substantial evidence base on which experts can draw to make expert elicitation useful."

We note that, due to the makeup of the EPA PM EE panel, the issue raised by the CIRAA regarding management of conflict of interest is a valid concern. Many of the EPA PM EE panel had taken public position on the issues they were opining on, were reviewing either their own studies, or studies conducted by colleagues with whom they have close academic relationships.

The NRC CIRAA also notes: "Given all these limitations, there are few settings in which expert elicitation is likely to provide information necessary for discriminating among risk-management options. The Committee suggests that it be used only when necessary for decision-making and *when evidence to support its use is available.* The general concept of determining the level of sophistication in uncertainty analysis (which could include expert elicitation or complex QUA) based on decision-making needs is outline in more detail below."

Given the concerns expressed by the NRC CIRAA on the methodology and use of EE in risk assessment, we do not agree that EPA should use the results of the EE either qualitatively or quantitatively in the PM NAAQS review.

The Draft Guidelines Fail to Incorporate the Data Quality Act

The draft Guidelines fail to incorporate the Data Quality Act and related OMB and Agency Information Quality Guidelines. API strongly supports rigorous use of the 2002 OMB and Agency-specific Information Quality Guidelines to improve the "quality, objectivity, utility and integrity" of information that federal agencies "disseminate" to the public. As stated in the OMB guidance, risk assessments and other information must focus on the use of accurate, reliable, and unbiased information. Three important points from the OMB guidelines[12,13] are that:

- "[A]gencies shall adopt a basic standard of quality (including objectivity, utility and integrity) as a performance goal"

- Agencies should recognize a range of importance for governmental information; more important information, such as "influential scientific, financial or statistical information," should be held to a higher quality standard, with scientific or statistical results required to be "capable of being substantially reproduced"

- Agencies making health and safety-related decisions are directed to use the best available data

From API's perspective, the arguments for sound, quality data apply to EPA's economic analysis activities. In EPA's October 2002 Information Quality Guidelines, the Agency lists major work products undergoing peer review under the Agency's Peer Review Policy as "influential" information per EPA's Information Quality Guidelines.[14] To the extent that economic analyses are considered "major" under the EPA Peer Review Policy, the analysis should adhere to the Agency's Information Quality Guidelines.

Furthermore, OMB *Circular A-4* (page 17) specifically states: "Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies" ("data quality guidelines") http://www.wihtehouse.gov/omb/fedreg/rerpoducible.html.)"

The draft Guidelines should be revised to incorporate EPA's requirements to fulfill OMB's and the Agency's Information Quality Guidelines.

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[12] 68 Fed. Reg. 5492-5527.
[13] National Research Council of the National Academies, "Ensuring the Quality of Data disseminated by the Federal Government." The National Academies Press, Washington, DC, 2003.
[14] U.S. EPA. (October, 2002). "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency." EPA/260R-02-008. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf