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cc: Kyle Isakower <Isakowerk@api.org>  
Subject: API comments on 68 Fed. Reg. 5492 - 5527

Dear Sir or Madam:

Attached are a Cover Letter, Executive Summary, and Comments from the American Petroleum Institute on the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, and the OMB Draft Guidelines for the Conduct of Regulatory Analysis and Format of Accounting Statements (68 *Fed. Reg.* 5492 – 5527; February 3, 2003).

Please contact Kyle Isakower ([isakowerk@api.org](mailto:isakowerk@api.org)) of my staff or me if you have any questions.

**Howard J. Feldman**

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May 5, 2003

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Office of Management and Budget  
Office of Information and Regulatory Affairs  
1725 17<sup>th</sup> Street, NW  
Washington, DC 20503

RE: Comments on the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, and the OMB Draft Guidelines for the Conduct of Regulatory Analysis and Format of Accounting Statements (68 *Fed. Reg.* 5492 – 5527; February 3, 2003)

Dear Sir or Madam:

The American Petroleum Institute (API) appreciates the opportunity to comment on the notice cited above, which addresses issues associated with past and future risk and economic analyses conducted for regulatory purposes. API is a national trade association with over 400 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, OMB's draft report and guidelines have a direct and substantial impact on our members.

In the enclosed Executive Summary and Comments, API addresses all four areas for which comments were requested: 1) Costs and Benefits of Federal Regulations for FY 2002; 2) Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements; 3) Approaches to Analysis and Management of Emerging Risks; and 4) Suggestions Regarding Regulations Related to Homeland Security.

Our comments emphasize the following points:

- Uncertainties in various aspects of risk modeling are compounded in the final risk analysis. Causes of uncertainties include lack of exposure data or use of outdated data, use of worst-case assumptions for input parameters, use of outdated, flawed or unvalidated models, and uncertainties within modeling algorithms themselves.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.
- We recommend that OMB acknowledge the uncertainty inherent in the benefits and costs identified in the FY 2002 Summary Report. Uncertainty should be explicitly quantified in future years' Summary Reports.

- An uncertainty analysis should be required on the most critical parameters affecting net benefit estimates for *all* economically significant regulations. Agencies promulgating regulations with impacts of \$100 million or more should be required to conduct a formal uncertainty analysis that is exhaustive in scope and detail 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), the scope and detail of uncertainty analysis could be adjusted accordingly.

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 Kyle Isakower (202-682-8314 or [isakowerk@api.org](mailto:isakowerk@api.org)) of my staff, or me (202-682-8340 or [feldman@api.org](mailto:feldman@api.org)) should you wish to request any of the cited documents, or if you have any questions regarding these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard Feldman", with a long horizontal flourish extending to the right.

Enclosures

cc: R. Cavaney  
B. Frick  
C. Sandler  
J. Ford  
H. Ng  
J. Felmy  
E. Murphy  
K. Isakower  
M. Meteyer

*API Response to  
Federal Register Notice, Volume 68, No. 22, February 3, 2003  
Office of Management and Budget  
Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations*

**EXECUTIVE SUMMARY:**

Agency rulemakings may contain numerous sources of uncertainty that are often not identified as being significant when drafting Regulatory Impact Assessments (RIAs). Specifically, risk-based rulemakings rely on models that attempt to mimic actual behavior of constituents in the environment and within receptors themselves. These models are often combinations of algorithms, each with its own associated uncertainty. For example, a regulatory assessment of risk will often include algorithms addressing emissions (or release) rate, dispersion (fate and transport) modeling, exposure of human and ecological receptors, and finally, the toxicology of the constituent of concern within the identified receptor. When these algorithms are used in concert to develop estimates of risk, the uncertainties are compounded, and can make the resulting risk estimate almost meaningless. Further adding to the uncertainty of the risk assessments are Agencies' frequent use of outdated, flawed or unvalidated models, and the use of highly uncertain or worst-case assumptions for input parameters to the models.

Given the high degree of uncertainty associated with risk-based regulations, it is imperative that a quantitative uncertainty analysis be performed for all proposed risk-based regulations. Economic (benefit-cost) analyses should also be conducted for significant rules, and should specifically incorporate the estimated degree of uncertainty. In addition, these analyses must be transparent, and available in a timely fashion to allow for meaningful public comment.

API is pleased that the Office of Management and Budget (OMB) is clearly placing greater emphasis on the use of benefit-cost and uncertainty analyses in its Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements (Appendix C). However, while many of the proposed changes to the OMB Guidance are positive, more can and should be done to further the goal of sensible regulation. In this document, API presents comments on each of the four major sections of the February 3<sup>rd</sup> Notice, the highlights of which are presented in this Executive Summary.

***Section I: Costs and Benefits of Federal Regulations for FY 2002***

- While OMB supports greater use of uncertainty analysis in Appendix C, there is no acknowledgement of the uncertainty inherent in the benefits and costs identified in the FY 2002 Summary Report.

## ***Section II: Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements***

- An uncertainty analysis should be required on the most critical parameters affecting net benefit estimates for *all* risk-based regulations. Agencies promulgating regulations with impacts of \$100 million or more should be required to conduct a formal uncertainty analysis that is exhaustive in scope and detail 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), the scope and detail of uncertainty analysis could be adjusted accordingly.
- API supports the proposed requirement for Cost Effectiveness Analysis for major rulemakings as it may facilitate consideration of more efficient ways to achieve benefits. However, a credible Benefit-Cost Analysis (BCA), including a formal treatment of uncertainty, is also necessary for major rules in order to gauge the overall merit of the proposed rule and alternative regulatory options.
- Given the methodological problems associated with “stated-preference” techniques such as contingent valuation, API recommends that they not be used in benefit-cost estimates in a *quantitative* way.
- Given the importance of the health benefit category in determining the sign and magnitude of overall net benefits, API recommends that OMB require that the value of reduced mortality of major rules be estimated by using value of statistical life year and value of quality adjusted statistical life year measures rather than using value of statistical life.
- Requiring a 3 percent discount rate as well as allowing a lower discount rate (e.g., 1 percent) for intergenerational impacts as proposed in the draft Guidelines is arbitrary and could result in deficient analyses. A more defensible guideline would be to require only the application of a 7 percent discount rate and to allow federal agencies to carry out sensitivity analyses using a range of alternative discount rates only if the appropriateness of other discount rates can be convincingly demonstrated.
- API recommends that in cases of “true uncertainty,” OMB require an agency to conduct additional research to better understand the risk *before* estimation of net benefits.

## ***Section III: Approaches to Analysis and Management of Emerging Risks***

- Rigorous implementation of OMB and agency data quality guidelines is essential for analysis and management of emerging risks.

- API supports the use of quantitative uncertainty analysis, and where appropriate, quantitative probabilistic uncertainty analysis.
- Uncertainties in various aspects of risk modeling (e.g., lack of exposure 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) are compounded in the final risk analysis. EPA has been lax in using a probabilistic uncertainty analysis (e.g., Monte Carlo simulation) of exposure data to better quantify these uncertainties. Probabilistic uncertainty analysis should be performed for risk assessments conducted for all rules, with specific requirements determined by the level of economic impact of the rule.

#### ***Section IV: Suggestions Regarding Regulations Related to Homeland Security***

- The Department of Homeland Security (DHS) should coordinate the regulatory requirements of the multiple agencies that regulate security in the various sectors of the petroleum industry to promote efficiency and clarity.
- Security regulations for the petroleum industry should be based on flexible, risk-based approaches.
- API supports the use of threat-evaluation tools such as Security Vulnerability Assessments (SVAs) to ensure that security resources (costs) are focused on the higher-risk assets resulting in overall improved security (benefits).
- API recommends that industry security-related documents and material be protected as exempt from FOIA.

*API Response to  
Federal Register Notice, Volume 68, No. 22, February 3, 2003  
Office of Management and Budget  
Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations*

Agency rulemakings may contain numerous sources of uncertainty that are often not identified as being significant when drafting Regulatory Impact Assessments (RIAs). Specifically, risk-based rulemakings rely on models that attempt to mimic actual behavior of constituents in the environment and within receptors themselves. These models are often combinations of algorithms, each with its own associated uncertainty. For example, a regulatory assessment of risk will often include algorithms addressing emissions (or release) rate, dispersion (fate and transport) modeling, exposure of human and ecological receptors, and finally, the toxicology of the constituent of concern within the identified receptor. When these algorithms are used in concert to develop estimates of risk, the uncertainties are compounded, and can make the resulting risk estimate almost meaningless. Further adding to the uncertainty of the risk assessments are Agencies' frequent use of outdated, flawed or unvalidated models, and the use of highly uncertain or worst-case assumptions for input parameters to the models.

Given the high degree of uncertainty associated with risk-based regulations, it is imperative that a quantitative uncertainty analysis be performed for all proposed risk-based regulations. Economic (benefit-cost) analyses should also be conducted for significant rules, and should specifically incorporate the estimated degree of uncertainty. In addition, these analyses must be transparent, and available in a timely fashion to allow for meaningful public comment.

API is pleased that the Office of Management and Budget (OMB) is clearly placing greater emphasis on the use of benefit-cost and uncertainty analyses in its Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements (Appendix C). However, while many of the proposed changes to the OMB Guidance are positive, more can and should be done to further the goal of sensible regulation.

**I. COSTS AND BENEFITS OF FEDERAL REGULATIONS FOR FY 2002**

The OMB draft report estimates annual regulatory benefits of \$135 to \$218 billion over the past 10 years compared to annual costs of \$38 to \$44 billion. There is little or no discussion of the uncertainty of these estimates and the implication is that societal welfare has been significantly increased due to the implementation of federal regulations. This is highly misleading, and had uncertainty been explicitly addressed in the discussion, a more realistic assessment (the error bands would likely be so large as to make any definitive statement comparing benefits and costs impossible) would have been forthcoming.

Most of the above stated estimated net benefits stem from relatively few rules that did not formally treat uncertainty in the analysis; it is important to note that most federal regulations fail a benefit

cost test. For example, Hahn<sup>1</sup> examined federal regulations issued between 1981 and mid-1996 and found that roughly 43 percent of 106 final regulations examined passed a neutral benefit-cost test. Hahn also found that the net benefits of regulations could have been increased by over \$280 billion if agencies had rejected regulations that failed a benefit-cost test.

## **II. OMB DRAFT GUIDELINES FOR THE CONDUCT OF REGULATORY ANALYSIS AND THE FORMAT OF ACCOUNTING STATEMENTS**

### **Analytical Approaches [68 Fed. Reg. 5516]**

OMB is proposing to require a Cost Effectiveness Analysis (CEA) for all major rulemakings for which the primary benefits are improved public health and safety. A Benefit-Cost Analysis (BCA) would also be required for major health and safety rulemakings to the extent that valid monetary values can be assigned to the expected health and safety outcomes.

API supports this requirement for Cost Effectiveness Analysis for major rulemakings as it may facilitate consideration in the rulemaking process of more efficient ways to achieve a given environmental benefit. However, a credible BCA is also necessary for major rules (including a formal treatment of uncertainty) so as to gauge the overall merit of the proposed rule and alternative regulatory options.

### **Estimation of Non-use Values and Contingent Valuation [68 Fed. Reg. 5519]**

OMB states on page 5519: “When practical obstacles prevent the use of direct ‘revealed preference’ methods based on actual market behavior to measure willingness-to-pay, you may consider the use of alternative ‘stated-preference’ methods based on survey techniques.” This would presumably apply, among other things, to estimation of non-use values – the value an individual places on an environmental resource even though the individual may never use or see the resource now or in the future. Non-use value includes bequest, existence and option values.

Estimating non-use values relies on hypothetical survey techniques (e.g., contingent valuation) 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 have little, if any, incentive mechanisms to prevent or minimize misstatement of true preferences. In addition, estimated non-use values via such 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 of non-use values via survey techniques are highly speculative, subject to manipulation, and highly uncertain, with the potential to significantly distort net benefit estimates. Given these methodological problems associated with “stated-preference” techniques, API recommends that they not be used in benefit-cost estimates in a *quantitative* way. It would be more appropriate that any non-use benefits that may be associated with a rule be described qualitatively in the RIA. This should reduce uncertainty in net benefit estimates, prevent the use of highly uncertain non-use estimates from driving net benefit estimation, and still allow for non-use values to be incorporated in the overall analysis. A careful

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<sup>1</sup> Hahn, Robert, Reviving Regulatory Reform: A Global Perspective, pp. 3-4, AEI Press c/o Publisher Resources Inc.: Washington, D.C. 2000.

characterization of a non-quantifiable variable can provide important input into the regulatory process.

An alternate (albeit less preferred) approach if stated-preference methods are used in net benefit estimation requires both Agencies and OMB to rigorously evaluate all uses of stated-preference methods against their suggested data quality criteria and the Data Quality Act criteria. The OMB's criteria for evaluating the validity and credibility of stated-preference estimates needs to be strongly and rigorously implemented (along with the Data Quality Act).

### **Monetizing Health and Safety Benefits and Costs [68 Fed. Reg. 5521]**

The largest category (in aggregate monetary terms) of environmental benefits found in many benefit-cost analyses involves estimates of “value of statistical life (VSL)” or “value of statistical life year (VSLY)” or the “value of the quality adjusted statistical life year (VQASLY)”.

OMB proposes to give agencies wide discretion in the choice of effectiveness measure. While there may be advantages of this approach, e.g., increased flexibility given to agencies, there are also downsides. The estimated net benefits of recent rules promulgated by EPA, for example the Highway Diesel Rule requiring the production of ultra-low sulfur highway diesel, have been overwhelmingly driven by the estimated value of reduced mortality via the VSL approach. Given the importance of this benefit category in determining the sign and magnitude of overall net benefits, API recommends that OMB require that the value of reduced mortality of major rules be estimated by using VSLY and VQASLY measures rather than by using VSL.

Valuing “statistical life years” is generally preferred to measurements of the value of “statistical life” as it allows for the possibility, for example, that a regulation that increases the probability of survival for octogenarians be valued differently than if the regulation increases the probability of survival of children. It should also be noted that quality adjusted life years is the preferred measure of effectiveness appearing frequently in the medical literature.

The analysis should also account, to the extent possible, for countervailing impacts of regulations on number of lives or life years saved. Compliance costs of federal environmental, health and safety regulations currently exceed \$200 billion annually.<sup>2</sup> This significant real cost to consumers 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].

### **What Discount Rate to Use [68 Fed. Reg. 5521]**

OMB proposes that a real discount rate of 7 percent should be used in the base case of the analysis when the main impact of the regulation is to displace or alter the use of capital in the private sector. As a general rule, API agrees with this proposal. This rate is justified, as it is a reasonable estimate

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<sup>2</sup> Actual social cost of regulations is likely much higher (up to 4 times as high in the long run) than compliance cost as macro effects such as slower growth in the capital stock is a likely consequence of excessive regulation [see, e.g., Hazilla and Kopp (1990)].

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 (say between 10 – 25%) could be justified, depending on the sector, as pointed out by OMB. Should it be determined that this be the case (e.g., that the regulation is displacing corporate capital), API recommends that OMB require the analysis to be conducted using a higher discount rate, as well.

The draft OMB guidance states that regulatory analyses should be carried out using both a 7 percent and a 3 percent discount rate. API believes that this guideline is arbitrary and could result in deficient analyses. A more defensible guideline may be to require the application of a 7 percent discount rate (per above OMB guideline) and to allow federal agencies to carry out sensitivity analyses over a range of discount rates that are consistent with the impacted population. Factors such as type of regulation, population and economic sectors impacted, opportunity cost of capital and type of economic distortions caused by the rule should be used to determine and defend alternative discount rates. For example, it would seem to make little sense in a benefit-cost analysis to use a 3 percent discount rate for a rule that significantly impacts the allocation of corporate capital.

The fact that distributional differences are common between regulatory beneficiaries and regulatory burden-bearers provides yet another rationale for a requirement that agencies perform a robust sensitivity analysis showing how net benefits vary depending on the choice of discount rate. Such analyses would provide decision-makers and the public critical information concerning how sensitive net benefits are to the selection of discount rate and the location of the “break even” discount rate (i.e., the rate where the present value of benefits equals the present value of costs). API strongly recommends that the OMB establish a 7 percent real discount rate as a “weak” default intended to permit ready comparison of benefit-cost analyses across agencies, and allow agencies to perform sensitivity analyses across a range of discount rates that are consistent with the specific subpopulations that would be impacted, if the appropriateness of these alternative discount rates can be convincingly demonstrated.

#### *Discounting Health Related Impacts*

API agrees with the OMB view, also in line with professional consensus, that future health effects, including both benefits and costs, “should be discounted at the same rate as generally used in both BCA and CEA.”

#### *Intergenerational Discounting*

API strongly recommends that the exception for so-called “intergenerational effects” be removed from the guidelines and that OMB should maintain the 7 percent “weak” default value, applied consistently across agencies. Virtually all regulations will impact future generations and hence such a guideline opens the door for an unjustifiably low discount rate to be liberally applied across a wide array of proposed regulations whether or not a lower discount rate is actually justified. API further recommends that OMB allow agencies to undertake sensitivity analyses using different discount rates if the appropriateness of these alternative discount rates can be convincingly demonstrated.

## Treatment of Uncertainty [68 Fed. Reg. 5523]

The OMB Guidance adds a new analytical requirement 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 should be required to conduct a formal uncertainty analysis that is exhaustive in scope and detail 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), 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 this case, 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. EPA has often relied on conservative, or “worst-case” scenarios, while others have recommended relying on informed judgment (e.g., a panel of experts involved in a Delphi experiment). 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 OMB require an agency to conduct additional research to better understand the risk before estimation of net benefits.

A prime example of a major rule being put forward without sufficient understanding of the causal relationship among variables is EPA’s standard for fine particulate matter (PM<sub>2.5</sub>). As stated by the White House Office of Science and Technology Policy: “...the database for actual levels of PM<sub>2.5</sub> is also very poor, and only a handful of studies have actually studied PM<sub>2.5</sub> effects, per se. And current data do not support clear associations...so that causality for the observed mortality and morbidity effects cannot be established.”<sup>3</sup> Studies (the so called Harvard Six Cities and American Cancer Society studies) cited by EPA as evidence in support of a PM<sub>2.5</sub> standard, as well as the reanalysis of those studies by the Health Effects Institute, failed to adequately assess the potential impacts of

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<sup>3</sup> 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.

cofactors such as ozone or sulfur dioxide.<sup>4</sup> It is imperative that the direction and magnitude of causality among variables be sufficiently understood 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.

### **III. APPROACHES TO ANALYSIS AND MANAGEMENT OF EMERGING RISKS**

API strongly supports rigorous use of the 2002 OMB and Agency-specific Information Quality Guidelines for analysis and management of emerging risks. 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<sup>5,6</sup> 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

Additionally, API strongly agrees with OMB’s draft guidance for “Quantitative Analysis of Uncertainty” as it pertains to emerging risks (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*

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<sup>4</sup> See Jones and Lieberman, “The Ongoing Clean-Air Debate: The Science Behind EPA’s Rule on Soot”, 2001

<sup>5</sup> 68 Fed. Reg. 5492-5527.

<sup>6</sup> National Research Council of the National Academies, “Ensuring the Quality of Data disseminated by the Federal Government.” The National Academies Press, Washington, DC, 2003.

*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.'*

API strongly supports the use of quantitative uncertainty analysis, and the use of quantitative probabilistic uncertainty analysis of all data used to develop significant risk assessments, especially for major rules as defined in Executive Order 12866. The uncertainty analyses provide information on the robustness of the hazard and exposure assessments feeding into the risk assessment, which is then used in cost/benefit analysis in major health-based regulations. Uncertainty analysis should be conducted separately on all significant portions of the hazard, exposure, and risk assessments. Conducting uncertainty analysis on the hazard and exposure data sets will more accurately account for the compounding uncertainties that result from combining these data into the final risk assessment. Additionally, it is critical that the uncertainty analyses be transparent, to give all stakeholders the opportunity to assess: (1) if all significant parameters were addressed; and (2) the degree of conservatism incorporated into the hazard, exposure and risk assessments, which compound the overall uncertainty in the final risk assessment.

API disagrees with EPA's current practice of using primarily *qualitative uncertainty analysis* in cancer risk assessments. For example, EPA derives cancer slope factors by using very conservative, linear, non-threshold dose extrapolation models. EPA has proposed, and API supports, use of quantitative uncertainty analysis, including probabilistic analysis, in the "Draft Final Guidelines for Carcinogen Risk Assessment" (2/27/2003). In these draft guidelines, EPA recommends an uncertainty analysis of: animal and human data used in hazard assessment; the model used to determine the slope factor; the parameters used in the model; and human variation. The draft cancer risk assessment guidelines are out for public comment concurrently with these OMB cost/benefit draft guidelines. The recently finalized health assessment on 1,3-butadiene is discussed below as an example of a grossly unbalanced health assessment that will directly impact risk assessments for future regulations, including regulation of mobile source air toxics.

Most experts agree that uncertainty within the exposure assessment is greater than that within the hazard assessment. This is due to: (1) a lack of exposure data; (2) use of outdated data as a result of lack of current data; (3) use of exposure models using combinations of algorithms, each with its own associated uncertainties; (4) use of outdated, flawed or unvalidated models; and (5) use of worst case assumptions for input parameters to the models. All of these uncertainties are significantly compounded in the final risk assessment. EPA has been lax in using a probabilistic uncertainty analysis (e.g., Monte Carlo simulation) of exposure data to better quantify uncertainty where data are used to promulgate health- and/or environmental-based regulations. In addition, conservative exposure and fate and transport models are used that are not transparent to the public and for which uncertainty analyses are lacking. With the degree of uncertainty unknown for the exposure assessment, the quality of the data are unknown, and questioned by the regulated public.

A large portion of API federal regulatory interaction is with the U.S. EPA, consequently, most of our comments in this section refer to EPA procedures.

## Ways in which “precaution” is embedded in current risk assessment procedures [68 Fed. Reg. 5499]

Agency rulemakings often contain numerous sources of uncertainty that are often not identified as being significant when drafting RIAs. Specifically, risk-based rulemakings rely on models that attempt to mimic actual behavior of constituents in the environment and within receptors themselves. These models are often combinations of algorithms, each with its own associated uncertainty. A regulatory assessment of risk will often include algorithms addressing emissions (or release) rate, dispersion (fate and transport) modeling, exposure of human and ecological receptors, and finally, the toxicology of the constituent of concern within the identified receptor. When these algorithms are used in concert to develop estimates of risk, the uncertainties are compounded, and can make the resulting risk estimate almost meaningless. Further adding to the uncertainty of the risk assessments are Agencies’ frequent use of outdated, flawed or unvalidated models, and the use of worst-case assumptions for input parameters to the models.

An example of existing risk assessment/regulatory practices with ‘embedded precautions’ is the August 6, 1998 Refinery Residuals Hazardous Waste Listings rule. API considers this to be an overly conservative risk analysis due to excessive and unjustified precautions embedded in the risk assessment. Although the risks from EPA’s own highly conservative risk assessments for the residuals of concern were less than  $10^{-5}$  for three of the four listed residuals (Crude Oil Tank Bottoms, Hydrotreating Catalyst and Hydrorefining Catalyst), all four residuals were listed as hazardous (Clarified Slurry Oil Tank Bottoms was the fourth listed residual). The uncertainties associated with the conservative assumptions associated with these risk assessments were never adequately addressed in the RIA. Over-precaution created uncertainty in the following areas:

- EPA assumed zero biodegradation rates in their groundwater model, despite the highly degradable nature of the constituents of concern;
- EPA based its listing determinations on deterministic modeling for groundwater pathways rather than making use of widely accepted Monte Carlo analyses;
- EPA greatly underestimated the distance between landfills and groundwater wells in its groundwater pathway analysis despite more reliable data being available from another EPA source;
- EPA failed to account for the use of run-on/run-off controls at land treatment units and failed to address errors in its risk assessment for home gardeners.

Most importantly, EPA never gave proper consideration to population risks (the highest calculated population risk from the four residuals was four cancers in 10,000 years) in their final analysis. Instead, the Agency relied on individual risk exposure scenarios that greatly inflated EPA’s risk estimates (though these risks were still marginal). A qualitative analysis of uncertainty could have identified the extreme uncertainty associated with the over-precaution EPA incorporated into its risk assessment. Without this analysis, the final rule was promulgated, at a cost of millions of dollars annually, with virtually no health or environmental benefits likely to be realized.

## **Examples of unbalanced risk assessment and management methods, as they pertain to emerging risks [68 Fed. Reg. 5499]**

API offers the following three examples of unbalanced risk assessment and management analyses:

### **1. EPA's Health Assessment Document for Diesel Engine Exhaust (EPA 600/8-90/057F)**

The Diesel Exhaust (DE) Health Assessment document, finalized in May of 2002, was the primary justification for the final health-based rule on diesel exhaust. This document is a good example of an unbalanced risk assessment, and does not provide an adequate uncertainty analysis for use in risk assessment and rulemaking.

The health assessment provided conflicting messages to decision-makers for lung cancer risk by providing both a qualitative and quantitative assessment of cancer risk assessment. The qualitative risk stated that DE is "likely to be carcinogenic to humans by inhalation." The quantitative estimate of risk was presented as ". . .an exploratory risk analysis [of diesel exhaust] shows that environmental cancer risks possibly range from  $10^{-5}$  to nearly  $10^{-3}$ , while a consideration of the numerous uncertainties and assumptions also indicates that lower risk is possible and zero risk cannot be ruled out." This is an extremely large range of uncertainty, with the risk of excess cancers ranging from none (0) to 1 excess cancer in 1000 people. API asserts that the uncertainty in the health assessment was not adequately addressed in the rule regulatory impact analysis. API also proposes that this range of risk is so large as to be meaningless. Furthermore, as is typical when presented with a range of risk, EPA and other agencies and states almost invariably select the most conservative risk estimate, in this case  $10^{-3}$ .

It should also be noted that the quantitative risk assessment was conducted against external expert advice. Two independent expert review panels have recognized the non-quantitative aspect of the relationship of diesel exhaust to increased risk of lung cancer. In the June, 1999 Health Effects Institute (HEI) Research Special Report of the Institute's Diesel Epidemiology Expert Panel<sup>7</sup>, the HEI Panel recommends against using existing human epidemiology studies (specifically the Garshick railroad worker studies and the Steenland trucker study) for quantitative risk assessment of diesel exhaust. The second expert panel to endorse a similar view was the Clean Air Scientific Advisory Committee (CASAC) of EPA's Scientific Advisory Board. The CASAC forwarded this opinion to EPA in their previous review of the EPA Health Assessment Document for Diesel Emissions (EPA 600/8-90/057D and EPA600/8-90/057E).

Further, EPA did not fully accept convincing data (developed by the CASAC Chair, Joe Mauderly) that the rat model for respirable particles (used in part to justify human health effects) is not representative of human exposure due to differences in respiratory tract physiology. In this case, EPA invoked uncertainty in the rat model relevance to humans in order to use the rat data to make the case for carcinogenicity.

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<sup>7</sup> Health Effects Institute (1999), Diesel Emissions and Lung Cancer: Epidemiology and Quantitative Risk Assessment. Available at [www.healtheffects.org](http://www.healtheffects.org).

There was also a lack of transparency in several areas of the health assessment. EPA gave only a qualitative description of how they conducted their “exploratory analysis” to derive quantitative estimates of cancer risk. Another example is provided in the calculation of the human continuous exposure concentrations (HECs), which integrates multiple sets of modeled data to derive the HECs. In this case, EPA stated that it did a sensitivity analysis for significant HEC parameters, finding two important, but they did not provide the sensitivity analysis itself for examination.

In summary, API submits that the Health Assessment Document on Diesel Exhaust is an unbalanced assessment that lacks a transparent evaluation and analysis of existing data. The document fails to provide a clear analysis of data uncertainties inherent in its conclusions concerning risk.

## **2. EPA’s recently released final Health Assessment on 1,3-Butadiene<sup>8</sup> (EPA/600/P-98/001F)**

EPA’s recently finalized (October 2002) health assessment of 1,3-butadiene provides a strong example of excess conservatism used in addressing an “emerging risk” to health, due to perceived uncertainties in the science.

EPA’s revised health assessment concludes that the cancer potency estimate for 1,3-butadiene is 0.08 per ppm, and the corresponding concentration in ambient air that is estimated to pose a one in a million lifetime excess cancer risk is 0.01 part per billion (ppb), or 10 parts per trillion. According to data presented in EPA’s final document, exposures in this range are below ambient, background airborne concentrations currently found in rural areas. The risk assessment is based on a high quality study of workers that showed only a weak association between leukemia and workplace exposures that often were in the range of 10 parts per million – or 1,000,000-fold above the level EPA estimates poses a one in a million cancer risk.

Using more conservative assumptions and mathematical models than commonly applied, EPA concluded that this compound is a “known human carcinogen” and revised its 1999 draft health assessment to suggest that butadiene is 20-fold more potent than indicated in the earlier draft. We believe that EPA did not produce an accurate, reliable and unbiased risk estimate for butadiene. The Agency disregarded specific SAB recommendations, and failed to recognize that their numerous “biased” choices were producing in the aggregate a scientifically implausible result.

- EPA ignored SAB advice to adjust for the apparent role of peak exposures. Many of the workers in the epidemiology study used in EPA's cancer risk assessment had very high “peak” exposures to butadiene. The SAB recommended that EPA exclude those exposures from its dose-response modeling. EPA disregarded this advice, the effect of which is to overestimate potency for ambient low-level exposure.
- EPA departed from its usual practice of using the maximum likelihood estimate of risk when deriving a cancer risk estimate from human data. In 1998 and 1999, EPA based its calculations

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<sup>8</sup> The finalized butadiene health assessment is a newly released document that is undergoing extensive analysis by interested stakeholders. The comments presented here are not intended to be exhaustive; detailed technical comments are currently being developed.

on the maximum likelihood estimate (MLE) of excess cancer risk, which is typical practice for human data, instead of the 95% upper confidence limit (UCL), which is usually used with animal data. In the final assessment, EPA switched to the UCL, even though it acknowledged that it “has historically used MLEs for cancer risk estimates from human data rather than upper bounds as used with animal data.”

- EPA did not use the model suggested by the SAB for estimating lifetime excess cancer risk in the general population. When estimating the excess cancer risk for the general population, EPA used cumulative lifetime exposure as the relevant measure of dose. The SAB urged instead consideration of a “windows of exposure” model that had been used previously by the National Academy of Sciences to estimate lung cancer risk from radon. EPA disregarded this advice, the effect of which is to overestimate potency for ambient exposure.
- EPA computed lifetime excess cancer risks up to age 85, instead of following the Agency’s standard practice of calculating risks to age 70. The SAB recommended that EPA follow its normal practice of calculating lifetime cancer risk up to age 70, yet the final risk assessment is based on an 85-year lifetime. Going to 85 years adds to the overstatement of risk caused by EPA’s use of lifetime cumulative exposure as the relevant measure of dose (described in previous point).
- EPA departed from its usual practice of basing estimates of lifetime excess cancer risk on general population leukemia mortality rates (as opposed to incidence rates). EPA typically derives its estimates of lifetime excess cancer risk for the general population by applying a calculated unit cancer risk estimate (based on human or animal data) to published data on background cancer mortality rates for the general population. However, in this instance EPA used cancer incidence rates for the general population, the effect of which is to overestimate potency.
- EPA applied an extra adjustment factor of 2 without scientific justification. EPA applied an adjustment factor of 2 to its cancer unit risk estimate “to reflect evidence from rodent bioassays suggesting that extrapolating the excess risk of leukemia in a male-only occupational cohort may underestimate the total cancer risk from 1,3-butadiene exposure in the general population” and a potential lack of statistical power for lung cancer. API is unaware of any prior EPA cancer risk assessment where such an adjustment factor has been used.
- Added health benefits from EPA’s highly conservative assessment of 1,3 butadiene are unlikely; however, the economic impact of this revised assessment will be considerable since the risk levels are below current ambient levels in relatively pristine, rural area of the US.
- Impacts from EPA’s assessment also include classification of 1,3 butadiene as a reproductive or developmental toxicant under California’s Proposition 65, requirement for stringent controls to reduce air emissions after Residual Risk Assessment under Clean Air Act Amendments, and changes to worker and customer communications.
- Despite significant deviations in health assessment procedures (and contrary to Agency guidelines and standard scientific practice), EPA did not follow acceptable practices by

submitting the health assessment document for another SAB review before finalization of the document.

Under the National Air Toxics program, EPA's revised potency estimate for 1,3 butadiene could lead EPA to conclude that all States and Counties in the US are currently above the one-in-a-million (1 in 10<sup>6</sup>) risk for cancer. API considers that release of this information to the public, without considerable uncertainty and sensitivity analysis of the health assessment and evaluation of the compounding effect from use of overly conservative defaults and models, would be scientifically irresponsible and unnecessarily alarm the public.

Use of this health assessment to justify reducing concentrations of 1,3-butadiene to below background ambient concentrations would prompt costly emission control initiatives with unknown health benefits.

### **3. The 1997 Ozone National Ambient Air Quality Health Risk Assessment<sup>9</sup>**

Since EPA notes that pollutants such as ozone have no discernible thresholds for health effects and that a zero risk standard is neither possible nor required by the Clean Air Act, both the Clean Air Scientific Advisory Committee and the Administrator concluded that scientific risk assessment must play a central role in setting the standards. The 1997 revision of the ozone standards provides a rich example of needed improvements in the current EPA approaches to risk assessment.

During this rulemaking the Agency produced three separate health risk assessments with varying findings concerning the relative stringencies of the current hourly standard and proposed forms of potential 8-hour average standards. As part of their submitted commentary, API conducted extensive sensitivity tests of the exposure and risk assessment models used by the Agency. Impacts of specific approaches and default assumptions were evaluated in optimized models offered to EPA for their evaluations of potential population risk. However, these findings were ignored in the Agency's efforts to promulgate a revised 8-hour average ozone standard of 0.08 ppm.

The Administrator based the 1997 revised ozone standard on projected risks of decreased lung function and pain on deep expiration in 'outdoor' children estimated to experience such effects, noting that differences between the 0.08 and 0.09 ppm 8-hour standards under consideration represented tens of thousands more children and hundreds of thousands more occurrences of adverse effects in these children in the nine urban areas assessed. Quantitative sensitivity testing of the Agency's risk assessment models with reasonable, documented alternative assumptions indicated that the compounded effects of such choices led to projected risks of reduced lung

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<sup>9</sup> Three documents contributed to the overall 1997 Ozone NAAQS Health Risk Assessment: Whitfield, R.G., Biller, W.F., Jusko, M.J., Keisler, J.M., 1996, *A probabilistic assessment of health risks associated with short-term exposure to tropospheric ozone*. Report prepared for USEPA OAQPS. Argonne National Laboratory; Argonne, IL, (June); Richmond, H. (1997) *Supplemental ozone exposure and health risk analysis*. Internal memorandum from H.M. Richmond to K.M. Martin, USEPA, AQSSD/OAQPS/OAR, RTP, NC, dated February 11, 1997, Docket No. A-95-56 Item IV-A-1; Whitfield, R.G., 1997, Letter report, *Sensitivity of Health Risk Estimates of Air Quality Adjustment Procedure*, prepared by Argonne National Laboratory for the USEPA, OAQPS, RTP, NC (June 30), Docket No. A-95-56 Item IV-A-10.

function and increased symptoms that were overestimated by orders of magnitude. This sensitivity analysis was acknowledged but not used by EPA.

In the 1997 revision of the ozone standard the Administrator also refused to assess the UVB ‘disbenefits’ of further reducing ambient levels of ozone. DOE analyses submitted to the Agency had indicated that the value of potential deaths from increased skin cancers and of cataracts from increased UVB exposures due to reduced ambient ozone levels was of sufficient magnitude to approximately cancel the EPA-estimated value of beneficial health effects from the revised standard. The DC Circuit Court of Appeals remanded EPA’s initial refusal to conduct the UVB risk assessment but the subsequent UVB assessment conducted by the Agency concluded that the UVB-ozone science was too uncertain to make any quantitative conclusions, even though similar evaluations of UVB-ozone issues earlier had proved sufficient to regulate CFCs.

Overviews of identified issues with the EPA ozone risk assessment are provided in (1) the March 12, 1997 cover letter to API comments on the revised ozone standard proposed at 61FR65716, (2) the April 29, 1997 supplemental API comments on the second and third Agency ozone risk assessments, at pages 17-35 of Appendix A of the March 12, 1997 API comments, and (3) the May 1997 API Publication FR2, Sensitivity Testing of the pNEM/O3 Exposure Estimates to Changes in the Model Logarithm. Suggested revised approaches to facilitating future ozone risk assessments are also discussed in the January 31, 2003 comments to EPA and CASAC in their consideration of the Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants. A more detailed discussion of the 1997 O3 NAAQS RIA and the UVB “disbenefits” analysis issues is contained at pages 12-13 of Appendix E of the March 12, 1997 API comments and in the more recent publication, EPA’s \$32 Trillion Negligible Risk, by B. Lieberman, Regulation (Fall 2002).

Clearly, EPA’s should have more fully considered comments and data indicating the over-conservatism inherent in their ozone risk analysis.

### **Balancing precautionary approaches with economic growth and/or technological innovation [68 Fed. Reg. 5499]**

In response to OMB’s request for examples of over-precaution in rulemaking, API cites EPA’s Highway Diesel Sulfur Rule<sup>10</sup>. Note that API’s comments on this OMB request for comment are specifically focused on benefit-cost analysis of EPA’s Highway Diesel Sulfur Rule. It should not be construed from these comments that API is seeking to reopen the Highway Diesel Sulfur Rule. API’s legal challenge of this rule focused on potential short-term supply shortfalls that could result from the rule’s implementation schedule.<sup>11</sup> Furthermore, the following comments do not address the recently issued NPRM for Non-Road Diesel Sulfur, where there have been effective stakeholder interactions in the development of an implementation schedule.

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<sup>10</sup> 66 Fed. Reg. 5002 (January 18, 2001)

<sup>11</sup> National Petrochemical & Refiners Assoc., et.al. v. Environmental Protection Agency, 287 F.3d 1130, 1145-6 (D.C.Cir. 2002). The court stated that if EPA promulgated a rule “that would in fact result in a diesel fuel shortage or energy crisis, it would be acting arbitrarily and capriciously—failing to give ‘appropriate consideration to cost and energy’ in setting emissions standards” under sections 202 and 211 of the Clean Air Act.

### *EPA Failed to Recognize the Capital Expenditures of Overlapping Requirements*

In its highway diesel sulfur rule, EPA failed to recognize the massive expenditures already required, or soon to be required, to meet ever-growing regulatory requirements, such as reformulated gasoline (Phase II), gasoline sulfur reductions, mobile source air toxics (MSAT), and the planned non-road diesel rule. Access to capital, construction and engineering resource limitations, and government permitting all impact industry's ability to meet the time frames for fuels reformulations envisioned by EPA.

### *EPA Did Not Adequately Account for Industry Costs nor Address the Potential of Supply Shortages, Regional Impacts, or End-User Fuel Costs*

EPA seriously underestimated the cost of producing and distributing highway ultra-low sulfur diesel fuel as well as the technology required to produce it. In spite of input from API and the National Petroleum Council to the contrary, EPA chose to believe that most refiners could produce 15 ppm diesel fuel by upgrading conventional hydrotreating units to add reactor capacity and by using improved catalysts. However, industry maintained that such an approach simply would not work for the majority of refiners who must treat large volumes of light catalyst-cracked cycle oil in order to maintain production supply. Treating these refinery streams will require much more extensive desulfurization techniques, including new hydrotreating reactors that can only operate at significantly higher temperatures and pressures than existing units. Not only did EPA fail to recognize this reality, but it based its cost estimates primarily on technology vendor estimates, which are historically low. Furthermore, EPA did not account for the significant volume of highway diesel fuel that may have to be downgraded in order to maintain the integrity of a 15 ppm sulfur diesel fuel.

EPA estimated the cost of its proposed highway diesel rule to be about 4.0 cents per gallon (cpg). The DOE<sup>12</sup> reported cost estimates ranging from 7.8 cpg for a revamp of an existing unit to 10.6 cpg for a new unit based upon a more realistic 15% return on investment (ROI) for industry investment. Hence, DOE projected costs twice to two-and-a-half times as large as EPA's estimates. We believe that the DOE estimates are based upon a more accurate characterization of technology performance, capital requirements, and level of return necessary to justify capital investment than the EPA estimates. Furthermore, API believes industry capital costs will be about \$8 billion, roughly double the \$4 billion projected by EPA (based on information from the National Petroleum Council technology assessments and the Charles River Associates (CRA) report.<sup>13</sup>

The EPA standards for highway diesel fuel create the risk for significant product shortages and price spikes at regional and national levels. Indeed, the NPC<sup>14</sup> concluded, "There is a significant risk of inadequate diesel supplies if the EPA's proposal for 15 ppm maximum sulfur on-highway diesel

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<sup>12</sup> DOE, *Modeling Impacts of Reformulated Diesel Fuel*, Draft Report, August 2000.

<sup>13</sup> Charles River Associates, *An Assessment of the Potential Impacts of Proposed Environmental Regulations on U.S. Refinery Supply of Diesel Fuels*, August 2000.

<sup>14</sup> National Petroleum Council, *U.S. Petroleum Refining: Assuring the Adequacy and Affordability of Cleaner Fuels*, June 2000.

beginning April 1, 2006, is implemented.” The CRA report concurs with this view and assesses the magnitude of the market impacts that would stem from implementation of the EPA rule.

The CRA report found that the EPA-highway diesel sulfur rule could result in a 320 thousand barrel per day (MBD) supply shortfall, more than 12% of the 2007 Baseline Annual Energy Outlook forecast of domestic diesel production. Furthermore, the CRA report estimated diesel market price increases ranging from 15 cents per gallon to 52 cents per gallon depending upon the extent to which imports are available to dampen domestic market shortages.

In sum, the EPA did not adequately take into account the potential economic ramifications of its rule, despite being provided this information. Regional or national diesel shortages would prevent the timely transportation of critical manufacturing parts, health care items, military hardware and consumer goods (including foodstuffs) to areas where they are needed. Both the NPC and CRA reports provide credible evidence that the potential for such shortfalls is real. The wide range and depth of technical expertise from industry, government and academia of the NPC and its associated advisory committees justified and demanded that its reported conclusions be taken with utmost seriousness in policy deliberations. Unfortunately, they were not. In addition, the comprehensive CRA analysis was inappropriately dismissed by EPA during the rulemaking process.

API’s full comments, dated August 14, 2000, justifying the arguments above can be found in the EPA Air Docket No. A-99-06.

### **Additional Comments Regarding Fuels-related Rulemakings**

In addition to the comments provided above, API offers the following points relative to recent fuels-related risk and economic analyses.

- *Peak benefits should not be counted on an annual basis.* The highest single day (or in some cases the third highest single hour pollutant emission rates) cannot be used to calculate annual benefits. In most cases, the benefits of lowering the emission rate to below NAAQS only exist for a few days or even hours a year. A better mechanism would be to count these benefits for the actual average number of days the NAAQS standard was exceeded.
- *NOx and VOC reductions do not necessarily result in ozone reductions.* For example, during fall, winter and early spring, ozone formation is not normally a problem. It is therefore inappropriate to credit Nitrogen Oxides (NOx) and volatile organic compound (VOC) reductions as providing ozone reduction benefits during this portion of the year. In addition, the atmospheric chemistries of ozone formation can be quite different in different areas of the country at different times of the year. There are often times when increased NOx concentrations scavenge ozone from the air. At these times NOx controls contribute what EPA refers to as “disbenefits.” These “disbenefits” need to be quantified and included as negative values in the total benefit calculations. Further, there are many southern areas where naturally occurring biogenic VOC formation is so large that it makes mobile source VOC’s inconsequential. Since reduction of mobile source VOC’s in these cases provides no measurable reduction in ozone formation, no benefits should be attributed to these VOC reductions.

- *Better Modeling is Needed.* The old version of the non-road model predicted PM emissions based on fuel usage assumptions that totaled to 100% greater volumes of non-road diesel fuel than EIA reported used in recent years. Even the newly revised non-road model that was used in the recently issued Non-road Diesel NPRM, is based on assumptions that when totaled assume 25% higher volumes of non-road diesel fuel than are sold during the year. One way to improve EPA's modeling is to open these models to more peer review. However, EPA appears to be moving in the opposite direction. As a case in point, EPA is not allowing peer review of its new MOVES model.
- *Apply Risk Analysis Where Appropriate.* Most recent RIAs assume that EPA is correct in its predictions of the results of its technology forcing regulations. In reality, this is usually not the case. The 1992 highway diesel desulfurization rule was justified to enable PM traps, which were not needed and never installed on most highway trucks. All technology forcing programs have a significant chance of failure (note that the California Air Resources Board has now recognized the failure of electric vehicles to make sufficient advances). A risk analysis should be conducted to reflect the scientific uncertainty of proposed courses of action. In API's comments on the recent Highway diesel regulation, it was demonstrated that the relative risks of SCR systems for NOx reductions was significantly less than the risks of forcing NOx Adsorber technology. Current developments in Europe are confirming that analysis.
- *Need to compare proposed course of action to other alternatives.* EPA RIA's have often only proposed alternative courses of action that were obviously flawed, or assigned these alternatives a zero chance of success. RIA's must fairly assess all reasonable courses of action.
- *Modeling benefits claimed are often beyond the accuracy of data measurement that is input to the model.* In addition to building better models, regulators need to understand that it is only through understanding the accuracy of the modeling efforts that good decisions can be made. For example, Tier 2 benefits were based on a model prediction of an overall national drop in ozone of 0.3 ppm. The measurement accuracy of ozone monitors that provided the base information for the model is +/- 1 ppm at best. The overall accuracy of the Tier 2 modeling effort was at best +/- 5 ppm and thus the touted benefits may be within the statistical "noise." As such, there may be no real benefits realized when Tier 2 is fully implemented.
- *Incremental cost analysis is recommended.* All potentially significant increments should be evaluated. Often expensive increments are hidden within low cost options. For example, in the recent Highway Diesel regulation, 80% of the benefits could have been achieved at 20% of the costs by selecting a 30-50 ppm average sulfur fuel. A true evaluation of the incremental costs of requiring 15 ppm maximum sulfur diesel plus pushing technology to achieve a 90% emission reduction from previous standards revealed a cost effectiveness of about \$100-200,000/ton, without taking into consideration the increased risk of failure. However, this extremely high incremental cost was hidden by EPA's methodology that divided total costs by total benefits.

- *Unsupported assumptions cannot be used unless there is verification.* The Highway Diesel rule started with the assumption that Diesel PM is a likely carcinogen. It then assumed that all components of Diesel PM had the same carcinogenic effects. No toxicity or other data was presented that showed any correlation between specific compounds and carcinogenicity.
- *There is a need to follow up to determine if benefits are really achieved.* Many recent rules have used asthma reduction as a benefit. However, in spite of rule implementation asthma incidents continue to rise. EPA should provide data that indicates that implemented rules are indeed providing the benefits that were claimed at the time of promulgation. Regulations under the Clean Air Act have been implemented since the early 1970's and in many cases the current regulations are trying to capture the same benefits as previous rules.
- *The same benefits should not be used to justify multiple rules.* Tier 2 ozone benefits were also claimed under the Highway Diesel rule. Toxics benefits under the highway diesel rule were also claimed under MSAT. Later regulations should not be allowed to claim benefits that have already been claimed under existing regulations that have not yet been implemented.
- *Regulations should incorporate market driven incentives whenever possible.* New regulations should take into consideration normal market driving forces. Regulations that have punitive market impacts on those that comply encourage noncompliance. Whenever possible, regulations should be written such that the desired behavior is encouraged under normal market conditions. Note that the DOE alternative fuel regulations forced the purchase of expensive vehicles and fuels -- as a result, the desired results have not been achieved.

#### IV. **IMPROVING THE ANALYSIS OF REGULATIONS RELATED TO HOMELAND SECURITY**

Recognizing the vital importance of safe, reliable energy supplies to our nation's health, security has always been a top priority at petroleum facilities. From designing safe and secure facilities to protecting plants and infrastructure to training with local emergency response teams, companies have long recognized and responded to the need to protect their workers, communities, and energy supplies. Since September 11th, the petroleum industry has been broadly evaluating security at its facilities and voluntarily taking actions to improve security as deemed appropriate based on the size, geographic location, potential risk to workers and the surrounding communities, and potential likelihood of attacks.

While API has extensive experience in analyzing the costs & benefits of proposed regulations in general, regulations related to homeland security are a new reality and thus API has limited experience in this area. However, API does have recommendations on the administration and development of security regulations that may be developed for the petroleum industry.

First, API recommends that the Department of Homeland Security (DHS) coordinate the regulatory requirements of the agencies that regulate the various sectors of the petroleum industry. For example, a facility or asset in the petroleum industry may be regulated by the U.S. Coast Guard, Department of Transportation, and TSA. These agencies may have differing requirements and competing interests. Every effort should be made to coordinate the regulatory activities of these groups to ensure efficiency and clarity for industry and the government. Such coordination will reduce costs and increase the benefits of regulations.

Consistent with the idea of regulatory efficiency, API strongly suggests that potential homeland security regulations not attempt to include non-security related issues such as plant operations and associated materials and processes. These types of issues are covered under existing regulations such as the OSHA Process Safety Management program.

Additionally, security regulations for the petroleum industry should be based on risk-based approaches. Since the industry is comprised of many segments (e.g., exploration & production, transportation, pipeline, refining, marketing and marine) each with their own types of security issues, a prescriptive regulatory approach will be inefficient and ineffective. Rather, flexible, risk-based approaches that can be tailored for individual facilities or assets based on their particular operating characteristics and environments will provide benefits through improved security plans.

Risk management principles acknowledge that while risk generally cannot be eliminated, enhancing protection from known or potential threats can reduce it. While this is the case, it is important to make risk decisions about these threats using a systematic method such as a Security Vulnerability Assessment (SVA). SVA methods are tools that provide management with risk information based on a thorough, defensible process that evaluates the likelihood that a threat will harm a facility/asset and considers the consequences of that act. Use of such a method ensures that resources (costs) are focused on the high-risk assets resulting in overall improved security (benefits).

API further recommends that industry security-related documents and material be protected as exempt from FOIA and even classified as appropriate. In addition, API recommends that security regulations address the role of state and local governments to provide clarity to all parties involved. Finally, API recommends that at the onset of any discussions by the U.S. government regarding security-related regulations, that the appropriate industry be contacted to provide insight. Such discussions in a government-industry partnership are key to developing meaningful, effective and efficient security regulations.