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05/05/2003 05:19:23 PM

Record Type: Record

To: Lorraine D. Hunt OIRA BC RPT/OMB/EOP@EOP

cc:
Subject: OMB Cost benefit Comments

Dear Ms. Hunt,

Attached are the comments from the American Chemistry Council regarding OMB's February 3, 2003 FR Notice. Included are a (1) a cover letter (2) ACC's comments, and (3) four of five appendices. Appendix 1 is only available in hardcopy and will be arriving under seperate cover by regular mail. Please not that our comments include comments on the Draft Guidelines.

Thank you,

David Clarke

(See attached file: Cover Lttr for May 5 2003 Comments to OMB.doc)(See attached file: ACC Comments on OMB Feb 3 FR May 5 FINAL.DOC)

(See attached file: Appendix 2 - PCB.zip)(See attached file: Appendix 3 - TEQ.zip)

(See attached file: Appendix 4 Default Assumptions Table.doc)(See attached file: Appendix 5 Specific Examples.DOC)

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- Appendix 4 Default Assumptions Table.doc
- Appendix 5 Specific Examples.DOC

May 5, 2003

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202,
725 17th Street, NW.,
Washington, DC 20503

Dear Ms. Hunt:

The American Chemistry Council submits the attached comments on the *Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations; Notice*, which was published in the *Federal Register* on February 3, 2003.

The Council comprises the nation's leading companies engaged in the business of chemistry. Council members apply the science of chemistry to create innovative products and services that make people's lives better, healthier, and safer. The Council is also committed to improved environmental, health, and safety performance through its Responsible Care® Program; common senses advocacy designed to address major public policy issues; and health and environmental research and product testing.

In seeking comment on its draft report, OMB also sought the public's views on a number of extremely important issues pertaining to the practice of risk assessment and the nature of risk management decisions made by federal agencies. OMB also sought comment on its draft revisions to the OMB guidelines for regulatory analysis. I strongly urge OMB to consider these recommendations and to implement those that will best serve the public interest in a strong economy and effective, reasonable health, safety, and environmental regulations.

Should you need additional information on the Council's comments please contact David Clarke of my staff at (703) 741-5160, or via e-mail at (David_Clarke@americanchemistry.com).

Sincerely,

Joe J. Mayhew

COMMENTS TO THE OFFICE OF MANAGEMENT AND BUDGET

DRAFT 2003 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

68 FR 5492

February 3, 2003

Submitted on

May 5, 2003

The American Chemistry Council

Arlington, Virginia

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I. INTRODUCTION

The American Chemistry Council ("Council") is pleased to comment on the Office of Management and Budget's ("OMB") Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations (68 FR 5492-5527), which was released for public comment on February 3, 2003.

The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

In the year 2000, companies in the business of chemistry spent an estimated $19.7 billion to comply with all federal regulations. For these companies, this figure is equivalent to $19,000 per worker per year. The largest share (58%) is due to environmental regulation, followed by economic (15%), tax (14%), and workplace regulation (12%). Compliance with environmental regulation cost the business of chemistry $11.5 billion in the year 2000. Included in this category are regulations to control air and water pollution, reduce the risks posed by chemical products, and manage hazardous waste. About half of all environmental spending represents a recurring cost associated with pollution abatement control. About 30% of environmental spending is due to one-time capital costs. Hazardous waste cleanup represents 20% of environmental spending.

The Council recognizes that cost cannot serve as the sole basis for judging the value of federal regulations. Nevertheless, the magnitude of these costs raises serious questions about the cost-effectiveness of our nation's regulatory expenditures. For that reason, the Council welcomes OMB's requests for comments on the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations ("Draft Report") and the Draft Guidelines for the Conduct or Regulatory

Analysis and the Format of Accounting Statements ("Draft Guidelines").[1] The Council particularly appreciates OMB's interest in receiving comments on the U.S. government's approaches to analysis and management of emerging risks and how the U.S. government balances precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation. When risks are exaggerated rather than estimated scientifically and objectively, risk managers can be diverted away from managing meaningful risks, resulting in an inefficient use of resources that could be better directed toward higher priority problems. As our comments will indicate, we are concerned that current practices, especially at EPA, have followed this path.

The Council hopes these comments will assist OMB and others in the Executive Office seeking to improve federal regulatory analysis and management. The Council looks forward to working with OMB on this and similar matters in the future.

[1] The Draft Guidelines are appended to the Draft Report to Congress as Appendix C.

II. EXECUTIVE SUMMARY

As a fundamental principle, the Council and its members support health, safety, and environmental protection policies that incorporate risk-based priorities and cost-effective risk management. Essential to realizing such policies are well-conducted assessments of the costs and benefits of intended regulations, consistent with the regulatory principles of E.O. 12866, on "Regulatory Planning and Review." Moreover, as articulated in John D. Graham's September 20, 2001, memorandum on Presidential Review of Agency Rulemaking by OIRA, the risk assessments that are integral to this process should provide "an objective, realistic, and scientifically balanced analysis." Congress, in the Safe Drinking Water Act of 1996, also underscored as a national policy that agencies' science-based regulatory decisions for drinking water must use the "best-available, peer-reviewed science" and that agencies must present "comprehensive, informative, and understandable" information about the risks they regulate. OMB has recommended that agencies adopt or adapt these standards more broadly for judging the quality of scientific information they disseminate about risks they assess and regulate. Indeed, OMB has set high standards for scientific risk assessment for more than 15 years. Yet our experience is that EPA continues to issue guidelines and individual assessments that fall significantly short of the standards for objective, science-based, and realistic risk assessments (e.g., 2003 Draft Carcinogen Risk Assessment Guidelines and Supplement, EPA's chloroform risk assessment) through an over-reliance on highly conservative, "worst case" approaches, even for comprehensive assessments when more realistic information is available.

Even the most complete and data-derived risk analysis will require what the National Research Council's 1983 report, *Risk Assessment in the Federal Government: Managing the Process*, called "inferential bridges" (also, "risk assessment policy," etc., p3) or default assumptions to fill data gaps and scientific uncertainties. This does not mean, however, that it is acceptable to ultimately manage risk based on unjustified assumptions and policies that generate unrealistically biased and exaggerated risk assessments. Analyses that are purposely and sometimes highly conservative may be acceptable for early-tier screening assessments aimed at determining whether further investigation is needed, but they are not appropriate for end-stage

risk analysis that will drive risk management decisions. Yet – in a number of cases affecting Council members and other regulated entities – EPA later-stage risk assessments have relied on a cascade of conservative policy assumptions, despite more than a decade of attempts by OMB, Congress, and others to improve the Agency's practices.

The Council understands and supports the fundamental intention of OMB and the nation's regulatory system to achieve risk-based, cost-effective decisions, with appropriately applied precaution to deal with legitimate scientific uncertainties and data gaps. But, as more fully discussed in our comments – and detailed in Appendix 5 – the Council has deep concerns that decisions made in the name of environmental protection, and their supporting risk analyses, far too often embody an overly precautious, and often invisible, bias. Our comments provide not only the numerous specific examples cited in Appendix 5, but also provide a table in Appendix 4 listing the numerous conservative default assumptions embodied in EPA guidance and methodologies. We greatly appreciate OMB's initiative to better understand and remedy the continuing deficiencies in what should be an effective regulatory system that promotes the American public's interest in genuine health, safety, and environmental protection together with the economic prosperity and innovation that are the foundation for our other important goals.

The Council's comments respond to several parts of OMB's requests for comments:

- OMB's Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements ("Draft Guidelines"), Appendix C.

- U.S. approaches to analysis and management of emerging risks, with a particular focus on ways in which "precaution" is embedded in current risk assessment procedures and examples of unbalanced approaches to human and ecological risk assessment.

- Briefly, we comment on the question of how the U.S. balances precautionary approaches to health, safety, and environmental risks with other interests.

While we do not provide any suggestions on how to conduct better analyses of regulations related to homeland security, we do agree that these regulations can have significant costs and benefits that should be evaluated with the same degree of care appropriate for other kinds of

regulations. In addition, we would refer you to the Council's comments of May 24, 2002, in which we discuss the need for agencies to standardize their approaches to valuing effects and also comment on other issues pertaining to OMB's Annual Report to Congress on the Costs and Benefits of Federal Regulations, but we do not discuss the Draft 2003 Report in these comments. A summary of our recommendations on the above three issues follows:

I. The Council finds OMB's Draft Guidelines for the Conduct of Regulatory Analysis to be well written, comprehensive, and strongly grounded in economic theory and practice. We support OMB's proposal to have agencies conduct both Benefit-Cost Analyses and Cost-Effectiveness Analyses of regulations as a way to gain important additional insight into the merits of regulatory proposals. We also agree that analysis of 3% and 7% discount rates in evaluating future benefits and costs is an appropriate starting point, but also believe that as a sensitivity analysis higher discount rates should also be used along with these rates. Indeed, as OMB notes, at times much higher rates would be plausible. The Council agrees and recommends OMB establish a 7% real discount rate as a "weak" default intended to permit ready comparison, but require that agencies perform sensitivity analyses across a very wide swath of discount rates that could be reasonable under particular circumstances for specific subpopulations.

II. In seeking public comment on current U.S. approaches to the analysis and management of emerging risks, OMB specifically asked about ways in which "precaution" is embedded in current risk assessment procedures and sought specific examples of unbalanced approaches to human and ecological risk assessment. While other federal regulations besides those issued by the EPA impact companies in the business of chemistry, the Council's comments focus almost exclusively on EPA risk regulations because these have the greatest impact on our members and represent the most clearly illustrated, indeed sometimes egregious, examples of regulations that could be made more realistic and cost-effective. Besides the specific examples provided in the appendix, the Council makes a set of

core policy recommendations aimed at improving the conduct of risk assessment and management, none of them original but all of them important and needing more rigorous implementation to be effective.

III. The Council emphasizes the need to consider risk management in the context of other public values, including a prosperous economy and innovation, which can be harmed by lopsided and extreme precaution.

The Council's core policy recommendations for improving EPA risk assessments involve three fundamental changes to the Agency's practice and several improvements in risk assessment procedures that will assist in realizing these fundamental changes. While it is vital for EPA to take the immediate steps described below to improve Agency risk assessments, the Council also urges OMB to work with EPA to set in motion a long-term process of revising its risk assessment guidelines and methodologies to make them current with the scientific state-of-the-art and the high standard OMB has articulated for risk analyses. As noted above, none of the Council's suggested changes are new – rather, they are based on basic tenets of a science-based risk assessment process that were formulated years ago[2] but that EPA has yet to adequately implement. The Executive Office of the President – in a 1991 document titled "Regulatory Program of the United States Government" (EOP, 1991) – set forth the fundamental benchmarks that EPA's risk assessment process must live up to. A panel of 15 invited experts and 35 other participants also reviewed this document and concluded, among other things, that the continued reliance on worst-case assumptions distorts risk assessments. [Evans 1992] Quotes and key ideas in the following three points are taken from the EOP 1991 document:

- *EPA risk assessments must not "intermingle important policy judgments within the scientific assessment of risk" Rather, the "choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments.*" This principle is simple – risk assessments should aspire to the greatest extent possible to be objective scientific exercises that seek to realistically estimate risk. Risk management comes later, and

[2] See, e.g., NRC (1983); EOP (1991).

must be fully and transparently distinguished from risk assessment if the practice of risk assessment is to have scientific credibility.

- *Risk assessments should not continue an unwarranted reliance on "conservative (worst-case) assumptions" that distort the outcomes of the risk assessment, "yielding estimates that may overstate likely risks by several orders of magnitude*." Further, worst-case assumptions concerning actual human exposure should not be "used instead of empirical data," because they further exaggerate predicted risk levels. In short, risk assessments should use real data to the extent feasible; be as accurate, precise and realistic as possible; and should not seek to embed conservative policy preferences into what should be a policy-neutral estimation of risk. In cases where realistic knowledge/data concerning a risk scenario is unavailable, assumptions are often necessary, but to the extent that conservative assumptions are used in a risk assessment they must be clearly articulated for risk managers so that they fully understand how the analysis was performed, and where it may be overestimating risks.

- *Risk assessments should "acknowledge the presence of considerable uncertainty" and present the extent to which conservative assumptions may overstate likely risks*. They should not "routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action." Risk assessments should directly assess the impact of each choice or assumption and clearly communicate how these choices impact likely risks.

As discussed below, the Council urges OMB to work with EPA to immediately strengthen several risk assessment procedures and tools to foster clearer adherence to the three fundamental principles. These are:

⇒ *Risk assessors should present managers with a range of risk scenarios and fully disclose the plausibility of each to facilitate the risk manager's informed policy choices*. OMB must direct agencies in their risk assessments to consider multiple scenarios and to fully account for the plausibility or likelihood of each. Within this process, agencies must consider the highly

unlikely but plausible worst-case, the expected value or mean estimate of risk, and the reasonable best-case outcomes, without unduly emphasizing worst-case hypothetical scenarios. In presenting risk managers with a range of possible outcomes, accurately weighted for their likelihood, the goal of risk assessors should be to support the managers in making fully informed choices about both the appropriate degree of conservatism or precaution to adopt and the extent to which such choices may entail tradeoffs among other important factors (i.e., to facilitate the risk manager's informed consideration of benefits and costs). In comprehensively disclosing the features of their assessments, risk assessors must provide the empirical basis or scientific rationale for any assumption, conservative or precautionary policy choices used in a given scenario. They must also fully explain the implications of choosing a particular policy, including the countervailing risks and other effects that might arise directly or indirectly from a decision based on such policy choices. While default assumptions are required to fill data gaps and address uncertainties that arise in the conduct of a risk assessment, it is the risk manager's responsibility to ultimately decide how to address limitations in the risk assessment through additional safety factors and other policy decisions. Risk assessments must serve, not usurp, this process. As discussed in greater detail under Section 6 of these comments, one specific tool that would support risk managers in their role is greater reliance on Monte Carlo and other stochastic methods in conducting risk assessments. EPA has endorsed such methods for exposure assessments [EPA 1997], but has not facilitated their use by defining the process and data to be used.

⇒ *Agencies should assess scientific evidence using a weight-of-the-evidence process that is consistent, comprehensive, balanced, and reproducible*. Although EPA often describes the process it uses in toxicity assessments (and sometimes in performing exposure assessments) as a weight-of-the-evidence approach, in fact the Agency does not follow consistent, comprehensive, balanced, and reproducible procedures that external parties, such as the Council, can follow and understand. Such procedures assist the risk assessor

in deciding which data, both positive and negative, should be given more weight, and in determining how disparate data can be combined to reach a rational and scientifically supportable conclusion. To be useful and understandable to external parties, EPA's assessments must employ a more formal and transparent weight-of-the-evidence process (for example, the approach developed by Klimisch, et al., for evaluating data quality [Klimisch, 1997], the Bradford-Hill causation criteria cited below, and other such approaches that can make it clearer how EPA risk assessors judged the evidence they considered). A formal process would assign weights to data or apply carefully defined evaluation criteria to assist the risk assessor in deciding what data should be given more weight and in determining how disparate data can be combined to reach a rational and scientifically supportable conclusion. In addition, EPA's weight-of-the-evidence process must:

- *Place greater emphasis on human studies*. Although EPA states that human studies (including epidemiological studies) should be given more weight than animal studies, in practice the Agency does not consistently follow this policy. In particular, EPA sometimes dismisses epidemiological studies of any quality that do not show positive associations and accepts with little resistance studies that yield positive associations irrespective of their scientific quality. Epidemiological studies of highly exposed occupational cohorts provide important information on the human toxicity of chemicals and should inform EPA toxicity assessments to a much larger extent than at present.

- *Use causation analysis*. Causation analysis, sometimes referred to as application of the Hill Criteria (Bradford-Hill 1966), should be used to evaluate whether exposure to a particular chemical may cause an increased risk of disease. Specifically, causation analysis should be applied to a group of studies that have investigated potential

associations between exposure to a particular chemical and a specific disease endpoint.

It bears emphasizing that EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment unequivocally endorse the weight-of-evidence approach for evaluating epidemiological data applicable to a particular chemical and describe "well-accepted criteria for causation" that should be used in such an approach. At least 10 cause-and-effect analytical criteria have been proposed, according to EPA's document, though only six are described as "fundamental" criteria (EPA 1996, pD-9). Section 6 of the Council's comments cites in full the relevant portions of the EPA document, which reads in part, "Analyzing the contribution of evidence from a body of human data requires examining available studies and weighing them in the context of well-accepted criteria for causation." The proposed guidelines, along with other EPA guidelines and statements, suggest that Agency risk assessors well understand the scientifically correct procedures to undertake a proper weight-of-the-evidence evaluation, even if the experience of regulated entities indicates EPA is not fully utilizing this understanding in practice.

⇒ *Agencies should accept site- or chemical-specific data.* Although EPA recommends use of site-or chemical-specific data, it often does not accept their use, requiring instead that conclusive or unambiguous evidence be provided before a default value can be superseded. OMB should direct agencies to use site- or chemical-specific information first, and if these data are unavailable, an agency may consider a safety or default value consistent with the above recommendation.

⇒ *Agencies should fully implement the Information Quality Guidelines.* OMB should insist that federal agencies fully apply their Information Quality Guidelines in the course of conducting risk assessments, and should do so in a manner that is consistent with OMB's government-wide standards. Agencies should defer to studies that meet these guidelines and must set aside potentially influential information that is not transparent enough to be reproducible, or data deemed to be of questionable utility or integrity. In addition, information quality and applicability must be the primary drivers for

weight-of-the- evidence procedures, causation analysis, and the use of site- or chemical specific data (see above).

Lastly, when appropriate – for instance, when a pesticide is engineered for deliberate toxicity or a potent chemical's widespread use may create broad exposure – OMB should recommend ecological risk assessments be conducted on effects at the population and/or community level rather than on individual receptors.

Generally, the compounded conservatism of EPA risk assessments, together with a lack of uncertainty analysis, lead to regulatory decisions by both EPA, and state agencies that follow EPA's direction, that are unjustified relative to circumstances. This problem is readily apparent when overestimations of risk are used to justify CERCLA remedial actions. For example, the cost of remediating a site to a 1 ppm action level may be substantially higher than attaining a 5 ppm action level. Yet, because the risk assessments compile multiple layers of conservatism, both action levels are likely associated with no risk to the potentially exposed population and the costs incurred in attaining the lower level do not have any commensurate risk benefit.

Although, as noted above, the application of uncertainty factors and default assumptions is well accepted in risk assessment as a means to deal with data gaps and uncertainties, EPA risk assessments have employed judgments to inflate risk estimates beyond what is realistically justified by the scientific evidence. The Council's comments provide specific examples of EPA actions that, to use OMB's term, present highly "unbalanced" risk assessments. As a longer-term matter, OMB should work with EPA to plan and implement a program for upgrading Agency risk methodologies to reflect the state-of-the-science. This is imperative because EPA's risk assessments have far-reaching impacts on the U.S. economy, institutions, and public understanding of risks and should not be allowed to continue contributing to the "paranoia and neglect" that Dr. John Graham has accurately characterized as the state of our nation's risk management policies. Overall, our experience, as well as the concerns raised over many years by academic researchers and others who follow environmental risk issues, clearly point to the need for dramatic improvements in EPA risk assessments, including a more genuine application of the Agency's own scientifically sound and reasonable guidelines where available, such as the Agency's policy on probabilistic analysis.

The Council appreciates OMB's interest and efforts in fostering accurate, balanced and cost-effective risk assessment and risk management. Although the Council fully understands that an appropriate degree of caution should be used in making risk management decisions, such caution should be applied transparently in the risk management phase, and not opaquely in the risk assessment phase. Risk assessors, for their part, must seek to provide the best possible and most objective estimates of risk, fully disclosing any default assumptions necessitated by data gaps and uncertainties. If these fundamental changes are actually implemented in by EPA, all sectors will benefit.

III. COMMENTS

A. Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements

1. SUMMARY

Overall, the draft guidelines are well written, comprehensive, and strongly grounded in economic theory and practice. Several new parameters for regulatory analysis are proposed:

- Use of both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) in evaluating proposed regulatory actions
- Use of both 3% and 7% discount rates, and a 1% discount rate for regulatory actions with intergenerational effects (in addition to 3% and 7%).
- Conduct of formal quantitative uncertainty analysis (e.g., Monte Carlo analysis) for rules having an impact of $1 billion or more

The Council believes that the conduct of both BCA and CEA will greatly strengthen regulatory analyses since each addresses a different question. BCA addresses the question of whether a proposed regulatory action is "worth it" (i.e., do the benefits exceed costs) while CEA addresses the question of regulatory "effectiveness" (e.g., cost per unit of benefit, such as “lives saved”). For discount rates, selection of the most appropriate rate is dependent on factors such as the economic status of the population segment impacted (more wealthy segments may have lower discount rates vs. poorer segments) and the outcome being valued (e.g., health improvements vs. non-health outcomes such as energy consumption reductions). As such, we strongly recommend that agencies should not limit their analyses to a couple of arbitrary rates that may or may not be appropriate. They should begin with the consistent 7% discount value as a “weak” default value and perform sensitivity analyses across a very wide swath of discount rates that could be reasonable under particular circumstances for specific subpopulations. OMB must require that when an agency expresses a preference for a specific discount rate, it must provide to OMB a cogent economic rationale and support it with specific data for that regulatory action. We believe that OMB must direct agencies to scale the degree of uncertainty analysis based on the

impact of the proposed regulation rather than setting a hard and fast threshold (i.e., $1 billion). Finally, we believe that these draft guidelines would benefit from more consistent and transparent language related to the need for sensitivity analysis. OMB must clearly and objectively discuss the limitations associated with value of statistical life (VSL) estimates derived from occupational wage/risk premium studies. Overall, we believe that with these enhancements the OMB guidelines will provide sound regulatory analysis guidance and improve the utility and quality of economic information for regulatory decision making.

2. ASSESSMENT OF DRAFT OMB REGULATORY ANALYSIS GUIDELINES

a) Strengths of the Guidelines

These guidelines[3] are well written and clear in intent. OMB provides cogent explanations for several important economic principles (e.g., opportunity cost, benefits transfer). As the proposed guidelines have a number of strengths, only the most notable are described here. The first is OMB's clear emphasis on the need for agencies to evaluate alternative regulatory actions. OMB appropriately devotes an entire section of the guidelines (Section II) to describing possible alternative actions that should be considered (e.g., different enforcement methods, different degrees of stringency). We believe that OMB should direct agencies to perform these analyses, as too often agencies perform economic analyses limited to their preferred regulatory action rather than presenting benefits and costs of all reasonable actions. Evaluating all alternatives provides decision makers with the information needed to identify the alternative that "maximizes societal net benefits". We also support OMB's guidance that agencies identify and consider the undesirable side effects and ancillary benefits possibly associated with the proposed regulatory action. Many analyses to date have provided seemingly little attention to systematically evaluating the unintended consequences of proposed regulatory actions. Finally, the Council supports OMB's direction to agencies that they seek opinions, early in the analysis process, of those who will be directly affected by the regulation. In particular, industry is likely to have important information to offer to strengthen assessments, such as a better understanding of the

[3] Office of Management and Budget (OMB) Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, Appendix C: OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements. Federal Register 2003; 68(2):5492-5527.

opportunity costs (and not just *compliance* costs) of proposed regulatory action or potential unintended consequences. We believe that it is crucial for this information to be collected and appropriately used by the agencies in their regulatory analysis.

b) Areas for Improvement

We identified several areas where the guidelines could be strengthened. Sensitivity Analysis: In particular, OMB's discussion of the importance of sensitivity analysis is weak in spots. For example, OMB states that "it is *usually* helpful to provide a sensitivity analysis," but does not illustrate any situation when sensitivity analysis is *not* helpful.[4] OMB should take a much stronger stand in favor of routine performance of sensitivity analysis. An agency's failure to perform sensitivity analysis on parameters that have a material effect on net present value benefits should generally be interpreted as a serious analytic defect. Indeed, elsewhere OMB has stated called sensitivity analysis "an essential feature of high-quality analysis."[5]

VSL Estimation: There are only limited discussions regarding drawbacks associated with value of statistical life (VSL) estimates derived from occupational wage premium studies. Most VSL estimates used by agencies today are derived from studies of death rates by occupation and wage premiums associated with more "risky" jobs. A sentence on page 5519 (section IV a. 4, 2nd to last paragraph) describes two types of potential bias associated with these VSL estimates: differences in risk tolerance and differences in the "voluntariness" of risk in the study and populations affected by regulation. OMB should elaborate more on how the "voluntariness" of a risk can be objectively assessed, for the distinction between voluntary and involuntary risks is often more difficult to make in practice than it has been to describe in theory. Some risks that people often construe as voluntary have substantial involuntary components. Much of the risk associated with driving a car arises from the actions of others over whom we have no control.

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[4] See page 5514, col. 2, penultimate paragraph (emphasis added).

5 "…[S]ensitivity analysis is widely regarded as an essential feature of high-quality analysis, yet sensitivity analysis cannot be undertaken by outside parties unless a high degree of transparency is achieved. The OMB [information quality] guidelines do not compel such sensitivity analysis as a necessary dimension of quality, but the transparency achieved by reproducibility will allow the public to undertake sensitivity studies of interest." See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication, 67 FR 8456.

Some general cautions are presented about benefits transfer issues[6] associated with VSL estimates but nothing specific to occupational wage premium studies. Given the widespread use by agencies of VSL estimates from occupational wage premium studies, a more detailed discussion of the limitations of these studies is clearly warranted. One obvious problem is that the commodity valued in wage premium studies may be significantly different from the regulatory context to which an agency might want to apply it. Mortality valuations apply to much more complex commodities than they readily appear to.

In addition, OMB should provide a more thorough discussion concerning the accuracy of transferring VSL values from wage premium studies to regulatory contexts. Just as it is scientifically dubious to simply extract and apply risk estimates (such as IRIS values) without carefully considering the context, it is economically problematic to simply pull VSLs "off the shelf" without giving serious concern to whether the transfer is appropriate. For example, it has been routinely assumed that the risk premium embedded in wages corresponds to the *objectively estimated* level of the specific occupational risk in question and not what workers *perceived* its magnitude to be. VSLs are understated (overstated) if workers believe that the occupational risks leading to wage premiums are lower (higher) than they really are. Estimates from well-crafted hedonic models should not be applied without adjustment if actual and perceived risks are not the same. Agencies using VSLs derived from these studies need to carefully examine whether the VSLs were based on actual or perceived risk and adjust the VSL values they use accordingly.

The improper use of VSLs from wage premium studies poses potentially serious information quality problems. As OMB has elsewhere stated, the "objectivity" component of information quality applies to *both* original *and* supporting data. Regulatory Impact Analyses clearly qualify as supporting data, and the improper use of VSLs violates OMB's objectivity standard because it disseminates information that is inaccurate, unreliable and biased.[7]

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[6] Benefits transfer is defined as the transfer of existing estimates of non-market values from the context of a study to a new [policy] context

7 [… `O]bjectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods. See §V.3.b, 67 FR 8459 (emphasis added).

Benefit-cost Analysis (BCA)/Cost-effectiveness Analysis (CEA): OMB states that agencies should conduct both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) whenever possible. OMB's rationale is that both analyses have strengths and drawbacks and that the two techniques "offer regulators somewhat different but useful perspectives and more robust information about tradeoffs." In particular, the two analyses address different questions: BCA addresses the question of whether a proposed regulatory action is "worth it" (i.e., under what conditions do social benefits exceed social costs) while CEA addresses the question of regulatory "effectiveness" (e.g., cost [$] per life saved). As such, performance of both types of analysis will greatly strengthen agency regulatory analysis. We strongly support this approach and recommend that OMB require that agencies perform both types of analyses wherever it is feasible to do so, and make this requirement a standardized "robustness check" for RIAs. In cases where agencies fail to conduct both BCA and CEA, OMB should require that they document why it is infeasible to do so. Making both analytical approaches normal requirements will give OMB (and the public) important additional information to determine if the agency has appropriately implemented these guidelines.

Discount Rates: The guidelines indicate that agencies should use both 3% and 7% discount rates, as well as a 1% discount rate for regulatory actions with intergenerational effects (in addition to 3% and 7%). The concept of discounting is based on the knowledge that people prefer present to future consumption and later to sooner cost-bearing. Thus, future benefits and costs must be discounted—and at the same rate. This is true irrespective of whether the benefits and costs in question are realized in financial terms, health effects, or other units.

Individuals may "discount" benefits or costs further when their realization is uncertain. Just as uncertain future benefits have less value, uncertain future costs are less worrisome. This is not discounting per se but the impact of risk aversion. In this case, the commodity can be characterized probabilistically as a likelihood function of a specific event, where willingness to pay is lower for probabilities of less than unity. OMB should make clear that matters of risk aversion should not be intermingled with the choice of the proper discount rate, which speaks only to the rate of time preference in consumption.

In addition, individuals may "discount" future health gains more than they "discount" financial gains. This phenomenon may arise because of doubts about one's future ability to actually enjoy health gains. The extent to which a certain future health gain event will yield today's estimated level of utility is conditioned on future health status, which is uncertain. OMB should emphasize that uncertainty over the attributes of the future-realized commodity also affects valuation but is unrelated to the choice of discount rate. Agencies should not confuse or intermingle commodity uncertainty with rates of time preference.

After ensuring that they have not commingled various forms of uncertainty with time preference, agencies should then carefully examine the regulatory outcome being valued (e.g., health improvements; non-health benefits, such as energy consumption reductions) and attributes of the affected population (e.g., healthy adults, children; the elderly or infirm; wealthy or poor households, taxpayers) for insights into the choice of discount rate. Many of these attributes influence the determination of the appropriate discount rates. For example, lower discount rates are more likely to apply to children than the elderly and the infirm; and to wealthy households more than poor households. Where regulatory beneficiaries are the same as regulatory burden-bearers, the most appropriate discount rate must consider these factors. The choice of discount rate implies the prior identification of the attributes of the affected population.

Distributional issues arise, however, where regulatory beneficiaries are demonstrably different from regulatory burden-bearers. In this case, there is no value-neutral principle that can be used to determine which discount rate is "best." A "low" discount rate favors those who are on average younger, healthier or richer by embedding their likely preferences into the analysis. Conversely, a "high" discount rate favors those who on average are older, ailing or poorer. A regulatory program that is intended to make older, ailing or poorer household better off would fail to cost-effectively achieve its objective if alternatives are analyzed and compared using discount rates lower than those held by the target beneficiary subpopulation. Indeed, using an artificially low discount rate could easily result in selecting an alternative that fails to benefit the target beneficiary subpopulation at all.

The fact that distributional differences are common between regulatory beneficiaries and regulatory burden-bearers provides yet another rationale for agencies to perform a vibrant

sensitivity analysis showing how net benefits vary depending on the choice of discount rate. This analysis provides decision-makers and the public critical information concerning how dependent net benefits are on the selection of discount rate and the location of the "break even" discount rate (i.e., the rate where present value benefits equal present value costs). We strongly recommend that OMB establish a 7% real discount rate as a "weak" default intended to permit ready comparison, but require that agencies perform sensitivity analyses across a very wide swath of discount rates that could be reasonable under particular circumstances for specific subpopulations.

We believe that this proposed approach is the proper one for three reasons. First, it draws attention to the fact that discount rates vary in the population and that no single discount rate applies to all. The details of a specific regulatory action are important factors in determining which rate is most reliable. Second, it avoids the temptation for agencies to bury this potentially critical policy-relevant factor as an "economic policy" default assumption. As we address in other sections of our comments, agencies establish " policy" default assumptions or uncertainty factors that frequently engender tremendous controversy. The choice of discount rate is potentially another version of the same phenomenon. Third, our recommended approach reminds us all that the "right" discount rate may be a matter of genuine disagreement or policy controversy—especially in any case where regulatory beneficiaries are likely to have different rates of time preference than regulatory burden-bearers.

Where agencies express a preference for a particular discount rate, OMB's guidance must require the agency to provide a cogent rationale that is supported by specific theory and relevant empirical evidence that specifically applies to that regulatory action. Off-the-shelf defaults are inherently suspect, as are rhetorical arguments, hypotheticals, or unrelated precedents. This approach ensures consistency across agencies while permitting substantial flexibility (as long as it is exercised rigorously), and has great utility for setting priorities across government programs.

Discounting presents a clear case where existing variation across (and sometimes within) agencies undermines the public's capacity to make useful comparisons. OMB must set a high threshold for overcoming this consistent approach. The ability to perform programmatic comparisons is fundamental to the statute underlying this Report to Congress ("Regulatory Right

to-Know-Act") and is irreversibly harmed when agencies use inconsistent methods. Without consistency in discounting, potential health, environmental and safety risks cannot be assessed, compared and managed in an efficient and equitable fashion. Both the Administration and Congress lose their ability to prioritize programs and develop effective solutions.

Finally, with regard to a 1% discount rate for intergenerational effects, OMB provides no indication as to what may or may not constitute an "intergenerational" effect and thus threatens to undermine all that it accomplishes elsewhere with respect to discounting. *All* regulatory actions have intergenerational costs, as decisions made today reflect irreversible commitments of current and future resources and implicit decisions concerning what benefits to forego. In *some* cases, direct benefits are also intergenerational. It seems peculiar and seriously misguided to use completely different analytic principles for that small subset of cases where *benefits alone* are delayed by decades or centuries.

Apart from these concerns, there is little empirical evidence in the literature to support the choice of 1% over any other value. It appears that this special 1% rate is intended to apply to specific actions that are highly unlikely to yield net benefits under conventional methods. Further, this may embed controversial risk management preferences into what is supposed to be an objective analytic endeavor. We believe that this exception for so-called "intergenerational" effects must be removed from the guidelines and OMB should stick to a 7% "weak" default value, applied consistently across agencies, with additional requirements for robust sensitivity analysis of the effects of alternative discount rates across a very wide swath of discount rates that could be reasonable under particular circumstances for specific subpopulations.

Uncertainty Analysis: OMB indicates that agencies should perform formal quantitative uncertainty analysis (e.g., Monte Carlo analysis) for rules having costs of $1 billion or more. Clearly, uncertainty analyses will provide valuable information on the probability of occurrence (e.g., probabilities of harm to human health and safety) and aid decision-makers in determining whether to act now or seek additional information. However, defining any specific threshold will create incentives for agencies to avoid analyses by estimating impacts below the specified threshold, just as occurs today with OMB's $100 million threshold for economically significant regulations. More importantly, it makes no sense to establish any fixed threshold that triggers the

need for uncertainty analysis. The point of uncertainty analysis is to ascertain the expected likelihood that any fixed value will materialize. Equally disturbing is the presumption implicit in a fixed threshold that only uncertainty on the benefits side is important. Benefits assessments are already analytically richer than cost assessments; as OMB and others have frequently noted, agencies rarely, if ever, estimate opportunity costs. This is especially ironic because opportunity costs, which are benefits foregone, are so much more uncertain than direct benefits.

We believe OMB must establish a tiered approach and require that agencies scale the degree of uncertainty analysis to the level of impact of the proposed regulation. For example, for regulations having impacts of $1 billion or more a formal uncertainty analysis must be conducted, be exhaustive in scope and detail, and apply to both benefits and costs. Uncertainty analysis on the most critical parameters affecting net present value benefits ought to be performed for all economically significant regulations. For regulations with lesser impacts on the economy ($10 million to $100 million), the level of detail and scope of uncertainty analysis could be adjusted accordingly. In particular, OMB should seek uncertainty analysis on key regulatory determinants and model parameters, such as the uncertainty associated with projected costs for a regulatory action (to assess how likely it is that these effects will be unexpectedly significant). Armed with some information on the uncertainties on both the benefit and cost assessments, OMB can work with agencies to determine what additional information could be collected to improve and further inform agency decisions.

B. U.S. Government's Approaches to Analysis and Management of Emerging Risks

OMB has requested comments on current U.S. approaches to analysis and management of emerging risks. Specifically, OMB has requested comment on the following issues:

- Ways in which "precaution" is embedded in current risk assessment procedures through "conservative" assumptions in estimation of risk, or through explicit "protective" measures in management decisions as required by statutory requirements as well as agency judgments.

- Examples of approaches in human and ecological risk assessment and management methods addressed by U.S. regulatory agencies (e.g., consumer product safety, drug

approval, pesticide registration, protection of endangered species) that appear unbalanced.

The comments that follow address these issues by primarily focusing on EPA risk assessment practices. We first address how "precaution" should be factored into EPA risk assessment. Relying on important work by the AEI-Brookings Joint Center for Regulatory Studies[8], we next focus on the extent to which EPA environmental decision-making is, in fact, based on objective, realistic, and scientifically balanced risk assessments. We then address the extent to which EPA risk assessments overestimate risk, concluding that typical EPA risk assessments overstate risk by a factor of ten and, in some cases, perhaps by a factor of 100. We then provide some comments on the societal costs of EPA's failure to appreciate the imprecision of its risk estimates when using such estimates to make remedial or regulatory decisions. Finally, we offer some thoughts on how EPA risk assessment practices can be improved to more accurately estimate risk and reduce costs to society. In an appendix, we provide examples of cases where EPA risk assessments have grossly overstated risks.

1. Use of "Precaution" in Risk Assessment

The Council supports the intended approach of the U.S. regulatory system to rely on objective, realistic, and scientifically balanced risk assessment, to separate risk assessment from risk management, and to emphasize cost-benefit analysis, as spelled out in E.O. 12866. In the Council's view, the general risk assessment/risk management model as described by OMB and federal agency guidelines can, if properly implemented, provide for appropriate precaution in the risk management process without confusing the science-based risk assessment process with policy judgments relating to precaution. In instances where the potential costs to society are high, it may be appropriate to take a more cautionary approach in the measures taken to address clearly identified risks. Indeed, the Council believes that many regulatory measures already in place embody this approach.

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[8] See Appendix 1 [W. Kip Viscusi and James T. Hamilton. April 1999. Are Risk Regulators Rational? Evidence from Hazardous Waste Cleanup Decisions (Working Paper 99-2). (Research support was provided under Cooperative agreement No. CR-823604-01 from the U.S. EPA Office of Policy, Planning, and Evaluation.)].

The Council also firmly believes that industry and government must work together to continually enhance the data used in risk assessments, with the goal of eliminating or reducing the need for default assumptions in the risk assessment process to the maximum extent possible. Using overly restrictive precautionary measures can deprive society of important benefits to human health, environmental quality, and improvements in the quality of life. The Council supports an approach that provides for a reasonable and cost-effective response whenever a risk assessment yields reasonable evidence of the risk of serious or irreversible harm to health or the environment because of a particular product or activity.

In the Council's experience, however, government agencies, including EPA, have gone well beyond a science-based approach in assessing and managing perceived risks. As detailed in Appendix 5 of this document, there have been highly unbalanced government interpretations of precaution that essentially reject sound science and hamper innovation, instead favoring exaggerated risk assessments as the basis for precautionary action.[9] Current EPA assessment practices and policies often have disregarded real-life data and site-specific information in favor of multiple layers of overly conservative default assumptions. The Council opposes decision-making processes that do not have a strong basis in science and objectivity. Besides citing examples in Appendix 5 of specific rules and decisions based on unbalanced applications of safety or uncertainty factors, the Council's comments also list in Appendix 4 the broad range of conservative default assumptions available through EPA methodologies, guidelines, and practices.

[9] Perhaps the most egregious example stems from a decision by Peruvian officials the 1980s. Based on USEPA studies, Peruvian officials wanted to reduce cancer risks associated with trihalomethanes ("THMs") in drinking water. To achieve this goal, these officials and others from neighboring Latin American countries abandoned chlorination of their drinking water supplies, thereby contributing to a cholera epidemic that killed at least 3,500 people. In response, the Pan American Health Organization sent a letter to then-USEPA Administrator William Reilly asking for a letter clarifying that chlorination to control waterborne diseases "should be afforded top priority." A World Health Organization official editorialized that the uncertainties associated with the THM cancer risk assessment should have been balanced against the "disaster potential of not disinfecting water supplies."

2. Whether Risk Truly Drives EPA Decision-making

Environmental regulation in the United States is based on a combination of technology-based controls and risk assessment. For example, the regulation of pollutant discharges to waters of the United States is based on compliance with technology-based standards, with residual risks being protected against by water quality-based effluent limitations. Under other statutes, like CERCLA, remedial standards are to be based primarily on risk; technological considerations may be relevant after it is determined that an unacceptable risk exists (e.g., if a landfill is deemed to pose an unacceptable risk, a cap meeting RCRA design standards might be installed).

Although science-based risk is intended as the basis of U.S. environmental regulation, scholars have questioned whether risk truly drives CERCLA remedial requirements imposed by EPA at various sites. In 1999, on behalf of the AEI-Brookings Joint Center for Regulatory Studies, W. Kip Viscusi of Harvard Law School and James T. Hamilton of Duke University's Sanford Institute of Public Policy used original data on the cleanup of 267 hazardous waste sites to examine whether factors other than risk influence remediation decisions [Viscusi and Hamilton, 1999 (Appendix 1)]. The authors collected cost information on all 267 sites and risk data on a subsample of 150 sites. This yielded a human health risk database with information on over 20,000 chemical risk pathways at the 150 sites, which enabled the authors to develop estimates of the number of cancer cases averted by remediation and the cost per case of cancer averted. In general, Viscusi and Hamilton found that, although decisions under CERCLA are supposed to be based on risk, other factors – such as economics and politics – seemed to bear more heavily on remedy selection than risk reduction

The authors found that although EPA regulation and guidance provides the decision maker discretion regarding whether remedial actions will be taken at sites with cancer risks between 10^{-4} and 10^{-6} – and also provides that remedial actions should achieve risk level within this same range – in practice the cleanup goal chosen by EPA is often more stringent than 10^{-6}. The authors attributed this finding to the fact that EPA guidance encourages conservatism in exposure scenarios (e.g., future residential land use is often assumed even if the surrounding area is industrial) and parameter assumptions (e.g., the 95 percent confidence limit on the estimate of

the mean concentration of the chemical is often used to represent a chemical's concentration at a site).

Viscusi and Hamilton concluded that, overall, CERCLA expenditures were not cost-effective when evaluated in terms of cancer prevention. The mean number of cancer cases averted per site over a 30-year period was 5.6, with a range from 0 to 652 and a median of 0.019. The authors reported that the mean cost per case of cancer averted was $11.7 billion. The median cost was $418 million. The range was from less than $20,000 to $961 billion. At only 36 of the 150 sites was the cost below $100 million per cancer case averted. These estimates use EPA conservative risk assumptions and assume no latency period. With adjustments for these factors, the median cost rises to above $1 billion per cancer case. The most effective 5% of all cleanup expenditures eliminated over 99% of the cancer risk. Stated otherwise, 95% of the costs are spent to address less than 1% of the risks.

Finally, Viscusi and Hamilton found it disturbing that the presence of actual risk to people based on current land use patterns did not increase the stringency of site cleanup goals. That is, pathways exposing current residents generally did not receive more stringent standards than pathways that might expose hypothetical future uses. The authors therefore concluded that EPA is failing to target its efforts to protect currently exposed populations. The authors concluded their analysis as follows:

> *EPA cleanup policies are an outlier among government regulatory programs on any efficiency basis, assuming cancer prevention is the primary objective. The benefits of Superfund cleanup are highly concentrated at a very small percentage of sites, with most cleanup actions failing any reasonable efficiency test. The . . . results highlighted the pivotal role of political factors for inefficient cleanups, whereas the most desirable cleanups were not influenced by voting rates.*

The findings of Viscusi and Hamilton lead to the important question of whether EPA risk assessment practices are the cause of the problems many external parties perceive in EPA risk-based regulatory and remedial programs. If, as the authors suggest, risk assessment is being used to justify decisions made for other reasons, and not as the basis for scientifically well-founded

regulatory and remedial decisions, only by raising the quality of EPA risk assessments can the problem be adequately addressed.

3. EPA Does Not Accurately Estimate Risk

There can be little doubt that EPA risk assessors deal with uncertainty in assessing risk by systematically overestimating risk. Indeed, EPA has explained its process as follows:

> *To account for these uncertainties and to acknowledge gaps in science, we build in safety factors in the risk estimates which tend to overestimate what we believe to be the actual risk. Where there is uncertainty or where our information is incomplete, we make assumptions that tend to overestimate the risks as a way to insure the public health is protected. . . . As a result, when we estimate that there is a one-in-one-million (excess) risk, the actual excess risk is probably much less and may even be zero.*

EPA (2000)

While it is a well-accepted risk assessment practice to use default assumptions in the face of uncertainties about toxicity and exposures, this practice should not be taken as a license to insert multiple layers of conservative assumptions that in the name of uncertainty distort scientific evidence so that assessments cease to bear any resemblance to objective, realistic, and scientifically balanced evaluations of the data. Understanding that EPA risk assessment intentionally err on the side of overestimating risks, it is natural to seek to determine the extent to which that is true. A few examples are sufficient to illustrate, qualitatively, that EPA risk assessments result in very large overstatements of risk:

In deriving quantitative estimates of chemical toxicity through the calculation of oral Reference Doses ("RfDs") or inhalation Reference Concentrations ("RfCs"), EPA divides measures of toxicity from animal or human studies to account for up to five possible causes of uncertainty. By convention, the uncertainty factors range from 1 to 10 and are usually combined by multiplication, not addition. The process of dividing toxicity estimates by uncertainty factors means that all issues of uncertainty are resolved conservatively. For example, where data from an animal study are used to estimate toxicity to humans, one uncertainty factor – often a factor of 10 – is used to account for the possibility that humans are more sensitive than the test species.

So, if the animal species and humans are equally sensitive to the chemical, this one factor alone assures that all risk assessments using the RfD will overestimate risk by a factor of 10. If the animal species is more sensitive than humans, risk assessments using the RfD will overestimate risk by more than a factor of 10.

Typically, the products of the several uncertainty factors used in deriving RfDs or RfCs are very large. For 213 out of 414 chemicals (51%), the RfDs or RfCs in EPA's Integrated Risk Information System (IRIS) database were derived using total uncertainty factors greater than 100 (IRIS, 2003). For example, in the case of EPA's RfD for PCB Aroclor 1254, four uncertainty factors were multiplied together and divided into a toxicity measurement from a Rhesus monkey study to calculate the human RfD: (1) a factor of three was used to account for the possibility that humans are more sensitive than monkeys; (2) a factor of ten was used to account for the possibility that some humans are ultrasensitive to PCBs; (3) a factor of three was used because the monkey study was not a full lifetime study; and (4) a factor of three was used because the toxicity measurement from the monkey study was a "lowest observed adverse effect level" rather than a "no observed adverse effect level." The total uncertainty factor was 300 (rounded up from 270, the product of the four uncertainty factors). As discussed in AMEC (2002) (Appendix 2), the evidence is that Rhesus monkeys are more sensitive than humans (not the other way around), that the "less than lifetime" uncertainty factor is unnecessary, and that an "interindividual sensitivity" factor of three is more than sufficient. Thus, the total uncertainty factor of 300 is clearly excessive.

In performing risk assessments for possible carcinogens, EPA uses "cancer slope factors" ("CSFs") to estimate toxicity.[10] CSFs are typically derived from high-dose animal study tumor frequency data using a hypothetical dose-response curve. Moreover, the CSF is taken from the upper bound slope of the hypothetical dose-response curve. Nearly 20 years ago EPA acknowledged that this approach overstates risk:

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[10] A CSF is the upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime of exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100. See www.epa.gov/iris/gloss8.htm.

> *It should be emphasized that the linearized multistage procedure leads to a plausible upper limit to the risk that is consistent with some mechanism of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown and may be as low as zero.*

EPA (1986).

The factors EPA uses to estimate chemical exposures are biased. EPA's "high-end" exposure assumptions are so conservative that the individuals EPA is seeking to protect could not reasonably be expected to exist. For example, in seeking to protect people from chemicals in soil, EPA imagines an individual who eats 200 milligrams ("mg") of soil every day as a child, then eats 100 mg every day for 24 or more years as a adult from the same area, breathes in dust from the same place every day, and has soil stick to his or her skin for an extended period of time over a large area of this person's body – again every day. If this person then grows up to be a construction worker, EPA assumes, without any supporting data, that the person eats 480 mg of soil per day on the job. This person is truly imaginary.

The conservatism of EPA's exposure assumptions is compounded by the fact that when an exposure assessment uses a number of data points (or assumptions) that are at or near their maxima (i.e., 95th percentile values), the resulting exposure estimate represents a condition which rarely, if ever, could occur. This is illustrated by Burmaster and Lehr (1991), in which the authors provide a simple relationship from probability theory that describes the likelihood of occurrence of an outcome based on a series of conservative assumptions. If, for example, three conservative (95th percentile) exposure estimates are multiplied together, the outcome actually represents the 99.99th percentile of exposure (not the 95th percentile exposure), based on the following equation:

$$1 - (1 - 0.95)^3 = 0.9999$$

In other words, only 0.01% of a given population (1 in ten thousand, or 10 in 100,000, or 100 in 1,000,000) would experience exposure at or greater than this level. Thus, if – for example – an EPA baseline risk assessment for a site predicted a 1×10^{-4} risk for the maximally exposed individual living near the site, and 10,000 people live near the site, then 0.0001 extra people (one one-thousandth of a person) would be expected to contract cancer from living near the site.

It can thus be seen that EPA risk assessments inaccurately estimate actual risk. But can one determine the extent to which EPA risk assessments overstate risks? Although we believe it is difficult to answer this question with a high degree of precision, as discussed below it is possible to make an order of magnitude estimate of the extent of risk overstatement inherent in EPA's risk assessment approach.

4. Societal Cost of EPA's Failure to Provide Reliable Risk Estimates

The fact that EPA risk estimates are highly biased is exacerbated by the manner in which risk estimates are typically expressed by the Agency. The Agency's risk assessment approach is mathematical – numbers are added, multiplied and divided in the risk assessment calculation and the risk estimate itself is presented as a number. Because of this mathematical approach, the general public and many regulators believe, contrary to the fact, that the risk assessment process produces risk estimates that are reasonably precise. EOP (1991). In other words, there appears to be a general belief that the outputs of risk assessment calculations can be used to predict the actual potential for injury or disease resulting from chemical exposure. EPA fosters this perception by the precision with which it presents risk estimates. EPA typically uses two significant figures in cancer estimates – e.g., "3.2×10^{-5}" – rather than simply expressing the risk as "less than 1 in 10,000."

The imbalance in EPA risk assessment practices, together with the suggestion of precision where little may exist, can have substantial economic significance because regulatory and remedial decisions are commonly made by EPA based on the incorrect belief that differences in risk estimates reflect actual benefits or detriments to human health or the environment. This problem is readily apparent when admitted overestimations of risk are translated into, or used as justification for, CERCLA remedial actions. For example, the cost associated with cleaning a site to a 1 ppm action level may be substantially higher than remediating the site to 5 ppm. Because of the misconception or misinterpretation of the precision of the risk assessment process, regulators often believe that there is an actual benefit to human health or the environment in attaining the lower remedial objective and, conversely, that there is an unacceptable level of risk reduction in attaining only the higher value. The fact is that, because of the highly conservative bias in Agency risk assessments, both of these action levels are in all

probability associated with no risk to the potentially exposed population and the costs incurred in attaining the lower level do not have any commensurate risk-reduction benefit.

EPA risk assessors may well respond to the criticism that the Agency fails to appreciate the imprecision of its risk assessments by pointing out that virtually all of its risk assessments conclude with a qualitative (not quantitative) discussion of uncertainty. Although that is true, it obscures the fact that EPA *risk management decisions* typically do not reflect the uncertainty in the assessment. Rather, EPA risk managers engage in discussions regarding whether a cleanup or other regulatory standard (e.g., water quality standard or maximum contaminant level) should be 1 ppm or 2 ppm without acknowledging that it likely makes no significant difference in risk (although it may in cost). The Council recommends that this issue be given high priority by OMB and that efforts be made to assure that EPA, as well as other federal agencies, make regulatory decisions that reflect the substantial uncertainty inherent in risk assessment.

5. Examples of EPA Risk Assessments that Inaccurately Estimate Risks

In this section we provide some examples (summarized from the fuller discussion found in Appendix 5) of EPA decisions made during Agency risk assessments that have resulted in substantial and potentially very costly biased estimates of risk. EPA decisions leading to overstatement of actual risks have been made in connection with all aspects of the human health and ecological risk assessment processes, including environmental sampling and data collection, exposure assessment, toxicity assessment and risk characterization. Both the Table 1 below and Appendix 5, containing the details, are divided into two major sections, the first of which discusses human health risk assessment and the second of which discusses ecological risk assessment. Within each major section, examples are organized by major steps in the risk assessment process.

TABLE 1 -- EXAMPLES OF EPA INACCURATE RISK ASSESSMENTS	
Human Health Risk Assessment ("HHRA")	
Exposure Assessment	
Name	*Summary*
Gas Turbine Ass'n	• EPA requiring that human health risk assessment ("HHRA") use

petition to "delist" gas turbines from MACT	exposure period of 70 years, rather than the conventional 30 years for this type of assessment. • EPA requiring that HHRA assume that maximally exposed individual never leaves home. • EPA requiring that HHRA use highest possible emission factor for gas turbines.
Fox River HHRA	• EPA deriving high, long-term, fish consumption estimate from study that did not measure long-term consumption instead of from study that did measure long-term consumption. • EPA using out-of-date chemical concentration data that do not reflect current exposure. • EPA assuming high consumption of fish species (carp) that is rarely eaten. • EPA using exposure periods that are about two times too long based on available data.
Hudson River HHRA	EPA's HHRA for the Hudson River overestimates human health risk because it grossly overstates the rate at which Hudson anglers consume fish from the River. Because EPA failed to conduct a Hudson angler survey, it needed to rely on studies of other water bodies. Although there are five studies that could be used to estimate fish consumption, EPA relied on a single study (Connelly et al. 1992) that reported consumption rates four times higher than the average of other, better conducted, studies. EPA's use of the 1992 Connelly study was inappropriate for several reasons. • EPA derived a consumption rate almost three times greater than the authors of the study found. • The study was not designed to assess consumption rates, but rather angler awareness of and knowledge about fish consumption advisories; as a result, numerous assumptions were required to generate consumption rates. • Individuals who do not respond to surveys of this type are likely to consume considerably less fish than individuals who do respond. The response rate reported by Connelly is on the low-end of acceptable standards, which biases fish consumption estimates toward higher level consumers • The consumption rates based on Connelly et al. (1992) are inconsistent with well-conducted studies of similar angler populations

	which are more appropriate for estimating rates of fish consumption for the Hudson.
Housatonic River HHRA	• EPA assuming excessive exposure frequency and duration (e.g., 61 days/yr for trespasser in inaccessible area for period of nine years). • EPA assuming excessive dermal contact (up to six square feet of skin covered with soil on each visit to site). • EPA assuming excessive soil ingestion (up to 100 milligrams of soil on each visit to the site). • Such assumptions used even though blood concentrations of nearby residents had been measured and were not elevated.
Manistique Harbor HHRA	The Baseline Human Health Risk Assessment (BHHRA) for Manistique Harbor calculated a cancer risk to the average and "high-end" recreational angler of 1.8×10^{-5} and 2.4×10^{-3}, respectively. For the "average" and "high-end" subsistence anglers the risks were 2×10^{-4} and 1.2×10^{-2}, respectively. These values were based on several overly conservative assumptions, including: • The high-end angler scenarios assumed 25% of the fish diet was carp, despite the finding that few if any Upper Peninsula anglers regularly consume carp. • It was assumed that subsistence anglers obtained 50% or 100% of their fish from Manistique Harbor. This was unlikely given the demographics of the population and the difficulty associated with fishing from the banks of the Harbor. Manistique Harbor is small, the banks are bulkheaded, and better and more accessible fishing areas on Lake Michigan are readily available. • It was also assumed that the anglers consumed fish from the Harbor 365 days a year. Since the Harbor freezes over in the winter, this assumption is wholly unfounded.
Change in adult default soil ingestion date	• Even though in 1997 EPA relied on a 1990 study to establish a default adult soil ingestion rate of 50 mg/day, in 2001, without explanation, EPA relied on the same study to change the default value to 100 mg/day. • EPA's has no scientific basis to change default value to 100 mg/day, especially since a 1997 study supports a default adult soil ingestion value of 20 – 40 mg/day.
Refusal to alter construction worker	EPA continues to use default construction worker soil consumption rate of 480 mg/day based on the conjectures found in Hawley (1985) even

soil consumption rate	though: • New measurements of soil to skin adherence show that the Hawley (1985) assumptions were excessive. • Using average and high-end soil adherence rates developed by an EPA workgroup, the construction worker soil ingestion rate ranges from 33 mg/day (average) to 64 mg/day (high-end).
EPA continues to use excessive dermal absorption factor for PCBs	EPA's dermal absorption factor for PCBs of 14% overestimates the fraction of PCBs that are absorbed through the skin because: • Study on which it is based used soil with very low carbon content. • Study methodology did not mimic expected chemical mixtures (fresh vs. weathered PCBs) or conditions of dermal exposure (24-hour monkey exposure through abdominal skin vs. shorter-term human exposure through hands) • Recent study using soil with 5-6% carbon content, weathered PCBs, and 12-hour dermal exposure period supports dermal absorption of approximately 4%.
EPA failure to perform probabilistic risk assessments	Although EPA guidance endorses the use of probabilistic risk assessment methodologies and has published detailed guidance regarding the topic, EPA ignores its own guidance. For examples: • The design of EPA's probabilistic model for the Hudson River was seriously flawed. The design forced EPA to assume that anglers consumed unrealistic amounts of fish harvested from the same locations, cooked in the same fashion, and composed of the same mixture of species every year for more than 30 years. The model did not account for variation in human behavior nor did it account for declining concentrations in fish tissue contaminant levels over time. • EPA Region 5 and Wisconsin Department of Natural Resources ("WDNR") conducted a HHRA that relied principally on a "point estimate" or deterministic approach in arriving at estimates of cancer and noncancer risk from consuming fish from the Fox River. Although the EPA/WDNR HHRA used certain probabilistic methods as part of a sensitivity analysis, the HHRA did not include a probabilistic risk assessment. The combination of incorrect input parameters for fish consumption, fish tissue concentrations, and population mobility, together with the multiplicative nature of deterministic risk assessments assured that the Fox River HHRA overestimated risk by up to several orders of magnitude.

Toxicity Assessment	
Name	*Summary*
EPA cancer risk assessment procedures	⬩ EPA generally requires use of linearized multistage ("LMS") model to estimate risk even though EPA knows the model "does not necessarily give a realistic prediction of the risk" and that "[t]he true value of the risk is unknown, and may be as low as zero." ⬩ EPA compounds the conservatism of the LMS by using the lower 95% limit on the dose that is estimated to cause a 10% response to derive a CSF, rather than a more central measure of dose. ⬩ Use of a model other than the LMS is permissible only if stringent conditions – which can rarely be met – are satisfied. ⬩ EPA will rarely give any weight to negative results in human cancer studies. ⬩ If human data are unavailable, EPA's default is that positive effects in animal studies mean the chemical may cause cancer in humans. Combined with preceding principle, this means that a single positive rat study may trump several negative human studies. ⬩ Another EPA default is that "effects seen at the highest dose . . . are appropriate for assessment," even though EPA knows that using maximum tolerated dose to project low dose effects is highly questionable. ⬩ A final EPA default is that "target organ concordance is not a prerequisite for evaluating the implications of animal study results for humans." This allows EPA to assume that a chemical is a human carcinogen even when there is evidence that humans do not contract the same type of cancer as test animals.
EPA's increase in IUR for 1,3-butadiene	In deriving new IUR for 1,3-butadiene, EPA: ⬩ Ignored SAB advice and excluded high exposure individuals from dose-response modeling, thus inflating the cancer estimate. ⬩ Departed from its practice of using the maximum likelihood estimate and instead used the 95% upper confidence limit, thus inflating the cancer estimate. ⬩ Ignored SAB advice to model risk using the window of exposure model, and instead used cumulative lifetime exposure, thereby inflating the risk estimate.

	• Without justification, used a longer than standard exposure duration (85 yrs rather than 70 yrs). • Without explanation, departed from its practice of estimating lifetime cancer risk using mortality rates (rather than incidence rates). • Contrary to guidance and accepted practice, and without scientific justification, applied a "gender uncertainty factor" in deriving the IUR. • Failed to give consideration to the cumulative impact of its many "health protective" choices, resulting in an IUR 20-fold more stringent than it proposed in 1999.
RfD for perchlorate	In January, 2002, EPA published a toxicity assessment for perchlorate, an anion that mimics iodide and may effect thyroid hormone levels. EPA recommended an RfD of 0.00003 mg/kg-day This value equates to a drinking water level of 1 ppb. There is no supportable scientific basis for the draft perchlorate RfD because: (1) the RfD is based on a NOAEL from highly suspect rodent data and application of an uncertainty factor of 300; and (2) the human data indicate that perchlorate is not toxic at levels at least 200 times higher than EPA's RfD. That evidence includes: • Perchlorate has been used as a medication to treat hyperthyroidism associated with Grave's disease. Adult dosages of potassium perchlorate of 200 – 900 mg/day produce clinical results. • Two human studies indicate no adverse thyroid or other health effects at perchlorate dosages up to 0.7 mg/kg-day. • A human volunteer study with 10mg/day perchlorate dosing for two weeks showed no changes to thyroid hormone levels. • Another human volunteer study, which EPA helped design, involved doses ranging from an equivalent of 200 ppb to 17,000 ppb perchlorate in water. No hormone effects were observed at the high dose. • Perchlorate occurs naturally in northern Chile. There were no adverse thyroid or any other health differences attributable to life long exposure to perchlorate at 110 ppb. • No differences in neonatal thyroid hormone levels or Medicaid data regarding prevalence of thyroid diseases or cancer were found in exposed and non-exposed infants from Las Vegas and Reno, Nevada, respectively. • There is no increase in neonatal hypothyroidism in southern

	California in zip codes associated with elevated perchlorate exposure. Based on the human studies and appropriate uncertainty factors, the RfD for perchlorate should be 0.005 to 0.17 milligrams per kilogram of body weight per day, equivalent to 175 to 6,000 parts per billion in drinking water.
Proposed RfD for acetone	EPA proposed an RfD for acetone of 0.3 mg/kg/day. This value is scientifically unsupportable because: • It is more than 100-fold below normal endogenous production of acetone in healthy individuals. Thus, a daily dosage of the magnitude of the RfD is meaningless from a toxicological perspective. • It is inconsistent with toxicity assessments performed by several other scientists and groups, including WHO, which has published a recommended value of 9.0 mg/kg/day, 30-fold higher than EPA's RfD • Acetone exhibited very low toxicity in 90-day drinking water studies sponsored by the National Toxicology Program ("NTP"). Minimally toxic concentrations were estimated to be 20,000 ppm or higher for males and females of different rodent species (20,000 ppm ≈ 1,700 mg/kg/day for male rats). NTP recommended against conduct of chronic studies because "the prechronic studies only demonstrated a very mild toxic response at very high doses in rodents." • In deriving the proposed RfD, EPA applied a combined total uncertainty factor of 3000, which is demonstrably overconservative.
Proposed RfD for trichloroethylene	To derive the RfD, EPA used an uncertainty factor ("UF") of 50 for human variation and values of 3 each for animal to human extrapolation, subchronic to chronic exposure, and LOAEL to NOAEL extrapolation. A "modifying factor" of 3 was also applied to reflect background exposure. This resulted in an overall UF of 5000, which was lowered to 3000, EPA's maximum UF. This UF is unnecessarily stringent because: • The human variation UF of 50 is inconsistent with EPA guidance. • The UF of 3 for subchronic to chronic exposure is unneeded because the dosing period in the animal study was chronic. • The LOAEL to NOAEL UF is unneeded because two of the three studies relied upon provided NOAELs or their equivalent. • The UF for animal to human extrapolation is unneeded because there is strong evidence that humans are less sensitive to the effects of TCE

	than are the most sensitive rodent test species. • Using a modifying factor to account for background exposure in the course of deriving an RfD is clearly inappropriate in risk assessment (such factor might be applied, if determined to be needed, in the risk management phase).
NTP's proposed listing of naphthalene as a carcinogen	NTP's proposal to list naphthalene as "reasonably anticipated to cause cancer in humans" is contrary to NTP's own guidelines in that: • There is no "limited evidence of carcinogenicity from studies in humans" because the only suggestions of an association between naphthalene exposure and cancer are seriously confounded. • There is not "sufficient evidence of carcinogenicity from studies in experimental animals" because the evidence is in one species, not multiple species; the evidence is at one tissue site, not multiple tissue sites; the evidence is from one route of exposure, not multiple routes; the evidence does not show an unusually high tumor incidence or other unusual characteristic; and there are "compelling data indicating that [naphthalene] acts through mechanisms which do not operate in humans."
EPA's new RfC for naphthalene	•EPA derived the RfC by applying an uncertainty factor of 3000 to a Human Equivalent Concentration of 9.3 mg/m^3, a value that is over 5 times lower than the occupational standard (TWA-TLV = 50 mg/m^3). •The naphthalene RfC overstates toxicity because of undue sensitivity of the animal model, the misapplication of uncertainty factors, and the stark contrast between the RfC and real-world exposure data (the RfC of 0.003 mg/m^3 is virtually identical to the background concentration for the chemical of 0.0052 mg/m^3)..
Hoboken, New Jersey, industrial building remediation	• EPA requiring remediation of building to unattainable standard of 0.44 μg mercury/m^3 of air even though OSHA standard is 100 $\mu g/m^3$, ACGIH standard is 25 100 $\mu g/m^3$, WHO standard is 25 100 ug/m^3, and lowest standard in any of 16 other countries is 20 $\mu g/m^3$. • EPA standard allegedly imposed to protect for workplace exposure, but calculated using residential assumptions. • EPA standard imposed even though the most reliable worker exposure studies show that 25 $\mu g/m^3$.is adequately protective.
PCB TSCA "Megarule"	• 1998 PCB remediation standards based on CSF of 4.0 $(mg/kg/day)^{-1}$ even though in 1996 EPA lowered the CSF to a maximum of 2.0 $(mg/kg/day)^{-1}$.

Gas Turbine Ass'n petition to "delist" gas turbines from MACT	• Inconsistent with guidance issued by EPA and other agencies, EPA requiring risk assessment to be performed using assumption that cancer and noncancer risks of chemicals are additive without any showing that the chemicals effect same target organ through same mechanism.
Use of Toxicity Equivalency Approach	• EPA advocating use of the "Toxicity Equivalency" ("TEQ") approach to assessing PCB toxicity even though approach is based on the unproven assumption of additive toxic effects, a significant amount of data indicate that TEFs are not additive, and TEQ approach substantially overpredicts the cancer and noncancer toxicity of PCBs.
Ecological Risk Assessment ("ERA")	
Toxicity Assessment	
EPA recommended "weight-of-evidence" approach to derive TRVs	Although recent EPA guidance discusses four methods that may be used to derive Toxicity Reference Values ("TRVs"), it recommends use of a method, the so-called "weight-of evidence" method, that will not generate TRVs that are appropriate for individual sites: • The method, which derives a TRV as the geometric mean of a variety of studies, may not use measurement endpoints that are relevant to key ecological receptors at particular sites (i.e., it generates generic TRVs). • For example, when evaluating studies for a weight-of-evidence assessment, less weight should be given to studies that evaluate the toxicity of the given chemical to receptors that are not found at the particular site or whose chemical form may not be relevant to the site-specific form.
EPA avian TRV for dioxin for the Hudson River	• On three occasions, EPA reviewed the toxicological data relevant to deriving an avian TRV for dioxin and decided that the TRV should be approximately equal to the NOAEL for dioxin from Nosek et al. (1992) study, which involved a 10-week exposure period. In so deciding, EPA determined that no subchronic to chronic uncertainty factor was needed because the study involved exposure throughout a critical life stage (reproduction). • Despite this precedent, EPA, in its ecological assessment for the Hudson River, used a TRV that was approximately 10 times lower based on the unwarranted assumption that the 10-week exposure period represented subchronic exposure.
EPA otter TRV for PCBs for the Hudson	For Hudson River otters, EPA developed TRVs based on data for mink. The TRVs are not scientifically supportable because the study used to

River	develop the TRVs included confounding exposures to pesticides and the authors did not attempt to segregate the potential contribution of the pesticides to the evaluated endpoint (kit survival).
Risk Characterization	
Fox River ERA	· Although an ERA is to consist of a "screening level" assessment followed by a detailed "baseline" ERA using site-specific data, final Fox River ERA is little more than a screening level assessment. · Although the ERA cites some of the voluminous site-specific ecological data that have been compiled, it ignores those data in arriving at its final conclusions.
Hudson River ERA	The Hudson River Revised Baseline ERA should not have been used to determine remedial action because the approach employed was designed for screening-level applications. · On behalf of EPA, Eastern Research Group coordinated a review of the ERA by seven independent peer reviewers. · Peer review group sharply criticized EPA's work product, concluding that EPA's ERA represented a screening-level effort and providing EPA specific recommendations to reduce the conservatism of and improve the ERA. · Peer review group unanimously agreed that EPA's characterization of the ecological setting was inadequate: "[W]ithout a description of the habitats, the species occupying the Hudson River, and the spatial and temporal use of habitats by species considered in the conceptual site model, the reviewers did not think it was possible to defend the risk characterization. . . . · EPA either failed to implement these recommendations, implemented the recommendations incorrectly, or made offsetting changes to the recommendations that resulted in little reduction to the level of conservatism.
PCB Worm Tissue Criterion for the Historic Area Remediation Site	In October 2002, EPA developed a proposed PCB worm tissue criterion for the "Historic Area Remediation Site" ("HARS"). The criterion is to be used to determine the suitability of dredged material for use as remediation material. The 113 ppb criterion is based on a number of overly conservative assumptions, including: · 100% of fish consumed by New Jersey anglers are sport-caught saltwater finfish.

	• 100% of the fish consumed are caught at the HARS. • All species consumed by recreational anglers are available at the HARS. • Anglers fish consistently every year for 70 years. • There is no loss of contaminants due to cooking methods. EPA ignored comment raising these issue, and promulgated the 113 ppb criterion in March 2003.
Tier II Great Lakes Initiative water quality criteria	In the Great Lakes Water Quality Initiative ("GLWQI"), EPA proposed a two-tiered approach to deriving water quality criteria. A Tier I water quality criterion is derived when specific data requirements are met . These data requirements are identical to those that EPA has used historically as the minimum requirements for calculation of ambient water quality criteria. Under the GLWQI regulations, a Tier II water quality value can be derived if the data required to derive a Tier I value are not available, or if the data are not of high quality. Because Tier II criteria are to be derived based on incomplete or inferior data, EPA builds in several levels of conservatism in the calculations. The approach can result in extremely low values, particularly when only a few acceptable toxicity studies are available, because the conservatism in the Tier II value increases as the number of suitable studies decreases. For example: • A comparison of chronic Tier I values for nine metals to their corresponding Tier II values show that the Tier II values overestimate the Tier I values from 3 to 16,000 times. • Use of the Tier II approach to develop a criterion for sodium chloride resulted in a criterion lower than naturally occurring levels.

6. Improving EPA Risk Assessments to More Accurately Estimate Risk

The issues presented in these comments are not new. As early as 1983, the National Research Council identified serious problems with the manner in which federal agency risk assessments were being conducted and recommended improvements to the process (NRC, 1983). The NRC's "Recommendation 1" was that as follows:

> *Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the*

> *consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies. . . . The goal of risk assessment is to describe, as accurately as possible, the possible health consequences of changes in human exposure to a hazardous substance; the need for accuracy implies that the best available scientific knowledge, supplemented as necessary by assumptions that are consistent with science, will be applied.*

NRC (1983).

These recommendations went largely unheeded. Twelve years ago, the Executive Office of the President ("EOP") reviewed federal agency risk assessments and concluded that risk assessments were unduly conservative and inappropriately imported policy judgments into what should be the science of risk assessment:

> *Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. . . .*
>
> * * *
>
> *The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude. Many risk assessments are based on animal bioassays utilizing sensitive rodent species dosed at extremely high levels. Conservative statistical models are used to predict low-dose human health risks, based on the assumption that human biological response mimics that observed in laboratory animals. Worst-case assumptions concerning actual human exposure are commonly used instead of empirical data, further exaggerating predicted risk levels.*
>
> Conservative biases embedded in risk assessment impart a substantial "margin of safety". The choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments. Estimates of risk often fail to acknowledge the presence of considerable uncertainty, nor do they present the extent to which conservative assumptions overstate likely risks. Analyses

> of risk-management alternatives routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action. Decision makers and the general public often incorrectly infer a level of scientific precision and accuracy in the risk-assessment process that does not exist.
>
> Conservatism in risk assessment distorts the regulatory practices of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address more substantial threats to life and health.

EOP (1991).

These three problems – policy judgments being inserted into the risk assessment phase, unjustified, overly conservative assumptions, and failure to acknowledge uncertainty – hamper risk assessment to this day, and have real consequences for human health, the environment, the federal budget, and private sector resources. Poorly done risk assessments can direct attention away from the actual source of risk. They also can lead to unnecessary expenditures of significant resources on insignificant risks, thereby reducing the resources available to address the significant risks. As new toxicogenomic tools are used, biased risk practices could damage the credibility of such tools, which otherwise might offer a solution to a number of the current risk assessment quandaries.

Fortunately, as discussed below, the means to improve EPA risk assessment are widely known, and implicit in EOP's 1991 critique of federal agency risk assessment. What continues to be lacking is the implementation of state-of-the-science knowledge and a discontinuation of widely discredited practices of the past. Leadership from OMB is needed to show other federal agencies, and particularly EPA, that better risk assessment and risk management decisions are possible and desirable. The Council's prescription for improving EPA risk assessment involves three fundamental changes in how risk assessment is performed today and several smaller changes that will assist in implementing the fundamental changes. These three key changes, as articulated in the 1991 EOP critique, are:

⇒ *EPA risk assessments must not "intermingle important policy judgments within the scientific assessment of risk*." Rather, the "choice of an appropriate margin of safety should remain the province of responsible risk-management

officials, and should not be preempted through biased risk assessments." This principle is simple – risk assessments should aspire to the greatest extent possible to be objective scientific exercises that seek to realistically estimate risk. Risk management comes later, and must be fully and transparently distinguished from risk assessment if the practice of risk assessment is to have scientific credibility.

⇒ *Risk assessments should not continue an unwarranted reliance on "conservative (worst-case) assumptions" that distort the outcomes of the risk assessment, "yielding estimates that may overstate likely risks by several orders of magnitude."* Further, worst-case assumptions concerning actual human exposure should not be used "instead of empirical data," because they further exaggerate predicted risk levels. In short, risk assessments should use real data to the extent feasible; be as accurate, precise and realistic as possible; and should not seek to embed conservative policy preferences into what should be a policy-neutral estimation of risk. In cases where realistic knowledge/data concerning a risk scenario is unavailable, assumptions are required, but to the extent that conservative assumptions are used in a risk assessment they must be clearly articulated for risk managers so that they fully understand how the analysis was performed, and where it may be overestimating risks.

⇒ *Risk assessments should "acknowledge the presence of considerable uncertainty" and present the extent to which conservative assumptions may overstate likely risks.* They should not "routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action." Risk assessments should directly assess the impact of each choice or assumption and clearly communicate how these choices impact likely risks.

The three fundamental changes described above should be applied to all phases of risk assessment, including toxicity assessment and exposure assessment. The following hypotheticals

should assist in elucidating exactly how toxicity and exposure assessments would incorporate these fundamental changes and how these tools can be applied. The point of these hypotheticals, which admittedly are somewhat simplistic, is to illustrate the difference between risk assessment and risk management, and to make clear the dangers of compiling layers of conservative assumptions in the course of risk assessment rather than leaving risk management decisions to the risk manager.

Exposure Assessment.

Assume the following hypothetical:

> *The Brown landfill is a lined landfill with leachate collection that was closed, capped and fenced in 1998. The existence of groundwater contamination (primarily elevated concentrations of Chemical Y) led to a Remedial Investigation/Feasibility Study that suggested a need for groundwater remediation. Remediation is now under way pursuant to a Consent Order with the landfill operator. Pursuant to the Consent Order, groundwater will be pumped from the subsurface, treated along with landfill leachate, and discharged pursuant to an NPDES permit. The cap will be inspected and, if needed, repaired, on a semi-annual basis. The cleanup has been funded for a period of 30 years. The landfill is in an industrial area and there is no reason to believe that the property will ever be used for any other purpose.*
>
> *Soil surrounding the landfill is contaminated with high concentrations of Metal Y, which is not volatile. Modeling shows that leachate from the soil will be collected by the groundwater wells and/or leachate collection system.*

Given these assumed facts, and applying the above principles, what exposure factors should be used in assessing the risk from the presence of Chemical Y in soils at the Brown landfill?

The Council submits that in this hypothetical there is only one plausible exposure pathway – soil ingestion by landfill workers. Dermal exposure is not a potential pathway because HAZWOPER requires that workers in a landfill environment wear protective clothing. The exposure frequency should probably be no more than twice a year – apparently the only time the landfill property needs to be entered. The exposure duration should be based on the estimated number of years a landfill worker might reasonably be employed in that capacity. The soil ingestion rate should be

no greater than EPA's default value of 50 mg/day. There is no reason to posit a construction scenario; thus a higher ingestion rate is unnecessary.

An EPA risk assessor would probably not agree with the above exposure assessment. Based on the Council's experience, an EPA risk assessor would make various assumptions regarding future occurrences that might increase human exposure to Chemical X at the Brown landfill, assume what the exposures might be under those assumptions, and calculate risk estimates based on assumptions regarding future conditions. For example, the risk assessor might assume that the fence would be torn down and trespassers would visit the landfill twice a week (even though the site will be managed for the next 30 years). The assessor might even assume that someday, when the landfill is finished subsiding and venting methane, if will become a residential neighborhood, and children will play on the contaminated soil 5 days per week.

Adopting such implausible and unscientific assumptions is not a proper function in risk assessment. The likelihood that the fence will be torn down or the landfill turned into a residential neighborhood cannot be calculated – they are not scientific issues. Rather, they are predictions about the future that raise policy issues such as how much money should be expended to protect against the low chance that a hypothetical trespasser 30 years in the future will like to visit the Brown landfill. Or about how much money should be spent to protect against the unlikely possibilities that someone, someday, will want to develop a residential community on a landfill and that, at that time, the government will allow it. These are decisions that are not within the purview of a risk assessment professional. They are policy issues that need to be addressed – openly and in detail – at a high level within EPA with, at minimum, the concurrence of the Regional Administrator.

Toxicity Assessment.

Assume the following hypothetical:

> *In White (1997)[11], rabbits were subjected to lifetime exposure to airborne concentrations of 0.1, 1, and 10 mg/m^3 of Chemical X. All the rabbits died at the 10 mg/m^3 exposure level within two*

[11] Note that the White, Jones and Brown studies referred to in the hypotheticals are themselves hypothetical.

days. None of the rabbits died at the 1 mg/m^3 exposure level, although there was some evidence of subtle neurological effects. No effects were seen at the 0.1 mg/m^3 exposure level.

Widget manufacturing workers were exposed to high airborne concentrations of Chemical X in the 1940s, but exposure levels were not documented. An epidemiological study of some of these workers at a plant in Chile (Smith, 2000) found a statistically significant excess of age-related neurological deficits.

In the United States, worker exposure to Chemical X was likely never as high as in Chile because U.S. plants used closed top widget immersion baths. Use of Chemical X was phased out between 1950 and 1965 as a dry process was developed for widget production. Occupational exposure measurements of workers at one U.S. plant in 1964 revealed that they had an average Chemical X exposure at that time of 3 mg/m^3. An epidemiological study of these workers (Jones, 1999) found no statistically significant association between Chemical X exposure and any disease.

Given these assumed facts, and applying the above principles, what should the RfC be for Chemical X?

The Council submits that the following analysis should be applied. Clearly 0.1 mg/m^3 is a NOAEL and 1 mg/m^3 is a LOAEL for Chemical X in rabbits. Jones (1999) suggests 3 mg/m^3 is a NOAEL for Chemical X in humans. Smith (2000) suggests that Chemical X may cause serious adverse effects in humans at levels that are probably significantly higher than 3 mg/m^3. Given the uncertainty that 3 mg/m^3 is truly the NOAEL for Chemical X in human since is based on only one epidemiological study, the point of departure for deriving the RfC for Chemical X should be the rabbit LOAEL 1 mg/m^3.

Given the above facts, the Council submits that the uncertainty factor analysis set forth in Table 3 should be applied:

TABLE 2 – THE COUNCIL'S RECOMMENDED UNCERTAINTY FACTOR ANALYSIS FOR DERIVING AN RfC FOR CHEMICAL X		
Source of Uncertainty	**Factor**	**Rationale**
Use of LOAEL rather than NOAEL	None	Although a LOAEL was used as the starting point, Smith (2000) suggests that the human NOAEL is higher than 1 mg/m^3. Therefore, use of 1 mg/m^3 as the starting point has already applied, in effect, a UF of 3.
Interspecies extrapolation	None	Not needed because the evidence is that rabbits are more sensitive than people to the effects of Chemical X.
Variation in human sensitivity	3	Generally, differences in sensitivity among human subpopulations are not large; usually the difference is less than a factor of 2 to 3, but occasionally is exceeds 5 (Price et al., 1999). Where the critical effect of the compound is well understood in humans and the sensitive population has been identified, the uncertainty factor for human variation can be reduced to as low as 1, as in the current RfDs for nitrate and fluorine (soluble fluoride) (Cicmanec and Pourier, 1995; EPA, 2003).
Extrapolation from subchronic to chronic exposure	None	White (1997) was a chronic study.
Database uncertainty	None	The weight of the evidence from three studies suggests strongly that the level at which Chemical X causes adverse effects in humans is well above 0.33 mg/m^3 (rabbit LOAEL of 1 mg/m^3 divided by UF of 3 for variation in human sensitivity).
Total uncertainty factor	3	

The RfC is therefore 0.33 mg/m^3 (rabbit LOAEL of 1 mg/m^3 divided by UF of 3).

Note that an EPA risk assessor would almost certainly establish a more stringent RfD based on this set of facts. This is true because EPA risk assessments universally violate the fundamental principles set forth above – they seek to be highly conservative, they apply policy judgments,

and they fail to appreciate the extent to which they compound conservatism. They do not seek to predict risk as accurately as possible.

For purposes of comparison, the Council sets forth below how we believe an EPA risk assessor would use the above hypothetical facts to derive an RfC for Chemical X:

EPA would agree that 0.1 mg/m^3 is a NOAEL and 1 mg/m^3 is a LOAEL for Chemical X in rabbits. EPA would also agree that Jones (1999) suggests 3 mg/m^3 is a NOAEL for Chemical X in humans. EPA would agree that Smith (2000) suggests that Chemical X may cause serious adverse effects in humans at levels higher than 3 mg/m^3, although how much higher is unknown. EPA would feel that there is substantial uncertainty regarding whether 3 mg/m^3 is truly the NOAEL for Chemical X in humans since it is based on only one epidemiological study. Thus, EPA would decide that the point of departure for deriving the RfC for Chemical X should be the rabbit NOAEL 0.1 mg/m^3.

Given the above facts, the Council believes that EPA would apply the uncertainty factor analysis set forth in Table 3:

TABLE 3 – THE COUNCIL'S PROJECTION OF EPA'S UNCERTAINTY FACTOR ANALYSIS FOR DERIVING AN RfC FOR CHEMICAL X		
Source of Uncertainty	**Factor**	**Rationale**
Use of LOAEL rather than NOAEL	None	Not needed because NOAEL used as starting point.
Interspecies extrapolation	3	Insufficient data to assume that rabbits are more sensitive than humans. (Based on experience, EPA might very well use a factor of 10.)
Variation in human sensitivity	10	Since no data are available for Chemical X, full factor of 10 applied.
Extrapolation from subchronic to chronic exposure	None	White (1997) was a chronic study.
Datebase uncertainty	10	Relatively few studies exist, so full factor of 10 is appropriate.
Total uncertainty factor	300	EPA virtually always multiplies, rather than adds, uncertainty factors.

EPA would therefore derive an RfC for Chemical X of 0.00033 mg/m^3 (rabbit NOAEL of 0.1 mg/m^3 divided by UF of 300).

Table 4 presents a comparison of the two hypothetical derivations of RfCs for Chemical X:

TABLE 4 – COMPARISON OF COUNCIL's AND EPA's RfCs FOR CHEMICAL X			
Factor	**Council**	**EPA**	**Reason for Difference**
Toxicity Assessment			
Point of Departure	rabbit LOAEL of 1 mg/m^3	rabbit NOAEL of .1 mg/m^3	Difference in weight given to negative epidemiological study
Exposure Assessment			
Use of LOAEL rather than NOAEL	None	None	None, although EPA would have applied a factor of 3 – 10 if it had

			used LOAEL as point of departure
Interspecies extrapolation	None	3	Difference in weight given evidence showing that rabbits are more sensitive than humans
Variation in human sensitivity	3	10	EPA almost always uses a factor of 10; the Council advocates 3 because the critical effect of Chemical X is well understood in humans, albeit in a population of workers who may have been healthier than other members of the general population. Because there clearly were no adverse effects in this human study, an uncertainty factor of 3 should be more than adequate to account for variation in human sensitivity.
Extrapolation from subchronic to chronic exposure	None	None	None
Datebase uncertainty	None	10	Council believes database to be unambiguous – human effects appear well above the Council RfD value. EPA applies full factor because few studies exist.
Total uncertainty factor	3	300	
Toxicity Characterization			
RfC	0.33 mg/m^3	0.00033 mg/m^3	

* * *

Although careful attention to and application of the three principles discussed and illustrated above should enable a risk assessor to produce an unbiased risk assessment, several tools exist that can be used to assist in this effort. All of these tools should assist the risk assessor to avoid including policy judgments within the risk assessment (leaving that to the risk manager) and

producing a risk assessment that, to the extent possible, neither overstates nor understates risk. These tools are summarized below. EPA guidance supporting the use of these tools is footnoted.

- *Risk assessors should present managers with a range of risk scenarios and fully disclose the plausibility of each to facilitate the risk manager's informed policy choices*. OMB must direct agencies in their risk assessments to consider multiple scenarios and to fully account for the plausibility or likelihood of each. Within this process, agencies must consider the highly unlikely but plausible worst-case, the expected value or mean estimate of risk, and the reasonable best-case outcomes, without unduly emphasizing worst-case hypothetical scenarios. In presenting risk managers with a range of possible outcomes, accurately weighted for their likelihood, the goal of risk assessors should be to support the managers in making fully informed choices about both the appropriate degree of conservatism or precaution to adopt and the extent to which such choices may entail tradeoffs among other important factors (i.e., to facilitate the risk manager's informed consideration of benefits and costs). In comprehensively disclosing the features of their assessments, risk assessors must provide the empirical basis or scientific rationale for any assumption, conservative or precautionary policy choices used in a given scenario. They must also fully explain the implications of choosing a particular policy, including the countervailing risks and other effects that might arise directly or indirectly from a decision based on such policy choices. While default assumptions are required to fill data gaps and address uncertainties that arise in the conduct of a risk assessment, it is the risk manager's responsibility to ultimately decide how to address limitations in the risk assessment through additional safety factors and other policy decisions. Risk assessments must serve, not usurp, this process.

  Greater reliance on certain tools can facilitate the risk manager's role in making choices. For example, although EPA has nominally endorsed Monte Carlo and other stochastic methods in conducting risk assessments [EPA 1997], the Agency has not defined the process or data would make these tools truly effective. EPA is in a unique position to evaluate, on a scientific basis, the quality of data for use in this application, but the Agency has not addressed this topic. As an example, Stanek and

Calabrese developed a soil ingestion distribution for children in a study that was funded by the EPA, but EPA has yet to endorse this data set as appropriate for this application. [Stanek, 2000, 2001] This reticence on the part of the Agency sends a signal that is contrary to EPA's 1997 policy, when in reality this is an area where EPA can clearly drive the science forward rather than continuing to use methods that are outdated and lead to the mis-allocation of limited resources to correct problems that will have little or no real impact on improving the public health. Probabilistic methods can also be applied to toxicity data. When data are clearly available, as in the case of higher-tier risk assessments, a probabilistic approach is the most scientifically appropriate. This will provide the risk manager with the proper frame of reference for making decisions, as opposed to the policy laden deterministic approach currently in place.

- *Agencies should assess scientific evidence using a weight-of-the-evidence process that is consistent, comprehensive, balanced, and reproducible*. Although EPA describes the approach it uses in its toxicity assessments (and sometimes in performing exposure assessments) as a weight-of-the-evidence process, in fact the Agency does not follow consistent, comprehensive, balanced, and reproducible procedures that external parties can clearly follow and understand. Such procedures assist the risk assessor in deciding which data, both positive and negative, should be given more weight, and in determining how disparate data can be combined to reach a rational and scientifically supportable conclusion. To be useful and understandable to external parties, the process EPA employs must be a more formal and transparent weight-of-the-evidence process, such as the approach developed by Klimisch, et al., for evaluating data quality (Klimisch 1997), the Bradford-Hill causation criteria cited below, and other such approaches that can make it clearer how EPA risk assessors judged the evidence they considered. A formal process would assign weights to data or apply carefully defined evaluation criteria to assist the risk assessor in deciding which data should be given more weight and in determining how disparate data can be combined to reach a rational and scientifically supportable conclusion. In addition, EPA's weight-of-the-evidence process must:

⇒ Place greater emphasis on human studies. Although EPA often states that human studies (including epidemiological studies) should be given more weight than animal studies, in practice the Agency does not consistently follow this policy. In particular, EPA sometimes dismisses epidemiological studies of any quality that do not show positive associations and accepts with little resistance studies that yield positive associations irrespective of their scientific quality. Epidemiological studies of highly exposed occupational cohorts provide important information on the human toxicity of chemicals and should inform EPA toxicity assessments to a much larger extent than at present.

⇒ Use causation analysis. Causation analysis, sometimes referred to as application of the Hill Criteria (Bradford-Hill 1966), should be used to evaluate whether exposure to a particular chemical may cause an increased risk of disease. Specifically, causation analysis should be applied to a group of studies that have investigated potential associations between exposure to a particular chemical and a specific disease endpoint.

The Council notes that EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment unequivocally endorse the weight-of-evidence approach for evaluating epidemiological data applicable to a particular chemical and describes "well-accepted criteria for causation" that should be used in such an approach. At least 10 cause and effect analytical criteria have been proposed, according to EPA's document, though only six are described as "fundamental" criteria (EPA 1996, pD-9). EPA's 1996 proposal reads:

> *Analyzing the contribution of evidence from a body of human data requires examining available studies and weighing them in the context of well-accepted criteria for causation. A judgment is made about how closely they satisfy these criteria, individually and jointly, and how far they deviate from them. Existence of temporal relationships, consistent results in independent studies, strong association, reliable exposure data, presence of dose-related responses, freedom from biases and confounding factors, and high level of statistical significance are among the factors leading to increased confidence in a conclusion of causality. Generally, the weight of human evidence increases with the number of adequate*

> *studies that show comparable results on populations exposed to the same agent under different conditions. The analysis takes into account all studies of high quality, whether showing positive associations or null results, or even protective effects. In weighing positive studies against null studies, possible reasons for inconsistent results should be sought, and results of studies that are judged to be of high quality are given more weight than those from studies judged to be methodologically less sound. Generally, no single factor is determinative. For example, the strength of association is one of the causal criteria. A strong association (i.e., a large relatively [sic] risk) is more likely to indicate causality than a weak association. However, finding of a large excess risk in a single study must be balanced against the lack of consistency as reflected by null results from other equally well designed and well conducted studies. In this situation, the positive association of a single study may either suggest the presence of chance bias or confounding, or reflect different exposure conditions. On the other hand, evidence of weak but consistent associations across several studies suggests either causality or the same confounder may be operating in all of these studies."(EPA 1996, pD-6-7)]*

- *Agencies should accept site- or chemical-specific data*. Although EPA recommends use of site-or chemical-specific data, it often does not accept their use, requiring instead that conclusive or unambiguous evidence be provided before a default value can be superseded. OMB should direct agencies to use site- or chemical-specific information first, and if these data are unavailable, an agency may consider a safety or default value consistent with the above recommendation.

  Where possible, risk assessments for specific sites should be based on reasonable and realistic exposure measurements or estimates for the site in question, not default or assumed values.[12] In determining the appropriate exposure area to be evaluated, the entire area that is equally likely to be contacted by the receptor should be considered, not just the contaminated portion of that area; otherwise, exposures will be

[12] See EPA (1992), at 93:

> The Exposure Factors Handbook is being updated to encompass additional factors and to include new research data on the factors currently covered. It also provides default parameter values that can be used when site-specific data are not available. Obviously, general default values should not be used in place of known, valid data that are more relevant to the assessment being done.

overestimated.[13] In determining exposure point concentrations for that area, agencies should estimate representative average concentrations using an appropriate statistical technique, rather than using maximum concentrations or statistical techniques that overestimate the true average.[14] In deriving values for other exposure parameters (e.g., exposure frequencies, amount of skin surface area exposed, food consumption rates, etc.), estimates and assumptions should be reasonable and realistic for the site, taking into account current and reasonably foreseeable site uses and conditions.[15] Use of probabilistic techniques to estimate exposures should be encouraged where appropriate.[16]

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[13] See EPA (1989), at 6-26:

> When evaluating chemical contamination at a site, it is important to review the spatial distribution of the data and evaluate it in ways that have the most relevance to the pathway being assessed. In short, consider where the contamination is with respect to known or anticipated population activity patterns. Maps of both concentration distribution and activity patterns will be useful for the exposure assessment. It is the intersection of activity patterns and contamination that defines an exposure area. Data from random sampling or from systematic grid pattern sampling may be more representative of a given exposure pathway than data collected only from hot spots.

[14] EPA (2001) defines the reasonable maximum exposure ("RME") as "[t]he highest exposure that is reasonably expected to occur at a site." EPA guidance (1992, 2001) recommends that, in developing the RME or "high end" exposure scenario, a combination of average and high-end exposure assumptions be combined to develop a "reasonable" estimate of maximum exposure rather than the worst-case hypothetical exposure imaginable.

[15] See EPA (1995) ("Land use assumptions affect the exposure pathways that are evaluated in the baseline risk assessment. Current land use is critical in determining whether there is a current risk associated with a Superfund site, and future land use is important in estimating potential future threats.").

[16] See EPA (2001). The guidance describes a tiered process for conducting HHRAs at complex sites. Beginning with deterministic point estimates, the analysis progresses, if warranted, to increasingly complex tiers of probabilistic analysis. The guidance makes clear that it is applicable to both human health and ecological risk assessments. Page xv states that "PRPs may submit work plans for probabilistic risk analyses for review during the risk assessment process or as required under legal agreements." The guidance also states that Monte Carlo analysis adds value whenever screening risk estimates exceed levels of concern and when the costs of remediation are likely to be high. Implicit in EPA's (2001) recommended progression from deterministic to probabilistic analysis is the realization that the point estimates are not an adequate means for basing risk management decisions at complex sites. According to EPA (2001) (at p.1-16):

> *The point estimate approach to risk assessment does not determine where the CTE or RME estimates lie within the risk distribution. ... Without knowing what percentile is represented by the RME estimate, the risk manager might be unsure about the likelihood of the RME occurring or being exceeded in the receptor population and about what level of remedial action is justified or necessary. . . .*

As a specific application of this principle, realistic default factors should be used in EPA's Soil Screening Guidance instead of the overly conservative values currently in place. This is especially important in the case of the factors for the migration-to-groundwater exposure route, which end up suggesting that very small amounts of soil contamination could contaminate groundwater, and therefore require full-scale risk assessments for chemicals that should be screened out early in the risk assessment process.

EPA should approve, in practice, the use of site-specific values in risk assessment and thereby follow and conform to the intent of its own guidance. If EPA were to do this, then many high-quality studies would be performed, e.g. field studies, land use studies, recreational surveys, etc., so as to improve the quality and accuracy of human health and ecological risk assessments.

- *Agencies should fully implement the Information Quality Guidelines*. OMB should insist that federal agencies fully apply their Information Quality Guidelines in the course of conducting risk assessments, and should do so in a manner that is consistent with OMB's government-wide standards. Agencies should defer to studies that meet these guidelines and must set aside potentially influential information that is not transparent enough to be reproducible or data deemed of questionable utility or integrity. In addition, information quality and applicability must be the primary drivers for weight-of-the-evidence procedures, causation analysis, and the use of site- or chemical specific data (see items above).

Lastly, when appropriate – for instance, when a pesticide is engineered for deliberate toxicity or a potent chemical's widespread use may create broad exposure – OMB should recommend ecological risk assessments be conducted on effects at the population and/or community level rather than on individual receptors.

By characterizing variability with one or more input distributions, the output from the Monte Carlo simulation is a distribution of risks that could occur in that population. The central tendency of the risk distribution (e.g. arithmetic mean, geometric mean, 50th percentile) may be characterized as the CTE risk estimate. Similarly, the high-end of the risk distribution (e.g., 90th to 99.9th percentile) is representative of exposures to the RME individual.

EPA (1997) ecological risk assessment guidance recommends that potential ecological risks should be assessed at the population-level for all but threatened and endangered species. Although no explicit guidance is provided, this is typically accomplished through the use of measurement endpoints that are related to population effects (e.g., using Toxicity Reference Values based on growth or reproductive effects). However, in many EPA ecological risk assessments, the agency has defaulted to assessing effects on individual animals. This metric has no significance scientifically and is entirely useless as a basis for making risk management decisions.[17]

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[17] See, e.g.:

EPA (1999), at 3,5:

> *Ecological risk assessments incorporate a wide range of tests and studies to either directly estimate community effects (e.g., benthic species diversity) or indirectly predict local population-level effects (e.g., toxicity tests on individual species), both of which can contribute to estimating ecological risk. Superfund remedial actions generally should not be designed to protect organisms on an individual basis (the exception being designated protected status resources, such as listed or candidate threatened and endangered species or treaty-protected species that could be exposed to site releases), but to protect local populations and communities of biota. Levels that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of-evidence approach.*
>
> *Superfund risk assessments should use site-specific assessment endpoints that address chemical specific potential adverse effects to local populations and communities of plants and animals (e.g., reductions in populations of fish-eating birds, or reductions in survival, reproduction or species diversity of indigenous benthic communities).*

USEPA (1994), at 1:

> *The ecological risk assessment of a Superfund site nearly always requires some type of field study. At a minimum, some field study is necessary in order to identify organisms and habitats that may be at risk" and "Rather than studying individual organisms, field studies generally focus on populations or communities. Populations are groups of organisms belonging to the same species and inhabiting a contiguous area. Communities consist of populations of different species living together.*

USEPA (2001), at 9, 52. This document reviews many of the principles to develop ecological management objectives. It states than an "ecological risk assessment examines many different species and multiple levels of biological organization, from individual to population, community, and ecosystem. " It emphasizes the use of Case Studies to explain the management objectives process, developing discussions concerning the importance of "reducing the level of toxic substances and by protecting human health, restoring vital habitats, and restoring and

C. Balancing Precaution and Other Societal Interests

OMB's F.R. notice also requests comment on how the U.S. balances precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation. In asking for comment on this issue, OMB raises a question with significance far beyond that of calculating benefits and costs of regulations for this nation. Technological innovation and economic growth are inseparable. When, despite reasonable measures to manage foreseeable risks, some government officials promote regulatory regimes that are so precautionary they thwart technological innovation, both the direct benefits of that innovation and the economic growth associated with it may be lost, or forestalled. This issue is discussed in a recent paper, "The True Cost of Precautionary Chemicals Regulation," which critiques the European White Paper "Strategy for a Future Chemicals Policy" and describes research that suggests the proposed strategy is "unrealistic and even unrealizable." (Durodié 2003)

For an economy – and an age – that is experiencing continual breakthroughs in biological sciences, nanotechnology, chemistry, and many other areas, it is imperative that our risk management systems not become an unreasonable obstruction to life-enhancing innovations. The key is to make reasonable judgments as to the appropriate balance between precaution and progress and to transparently and clearly describe the public interests being served by the decisions made, as well as the basis for the decisions. As has been said by local officials and

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mainlining stable, diverse and self-sustaining populations."

USEPA (2002), at 10. This draft SAB document provides guidance on assessing ecological conditions in an environmental assessment context, but many of its components are relevant to ecological risk assessments that assess chemical exposures. For example, it defines species or population measures as:

> *Measures of the condition or viability of populations of species in an area are important indicators, yet monitoring the status of all species is impossible from a practical standpoint. To address this problem, a higher taxonomic level can be used, or a subset of species called focal species can be monitored. Focal species are selected because they exert a disproportionately important influence on ecosystem condition or provide information about the ability of the system to support other species. In addition, some species such as endangered, rare, sensitive, and game species) require attention because they are of direct interest to society.*

others, federal laws and regulations to advance one goal – for instance, environmental protection – should not be implemented without regard for other equally pressing social demands, such as police, fire, and other services.

Evolving tools for evaluating comparative risks and countervailing risks make a valuable contribution to a more holistic understanding of the tradeoffs inherent in many decisions and should be resorted to more routinely by federal agencies in setting priorities. Just as decision makers now consider environmental consequences when weighing the merits of many proposed activities, including, for instance, new housing and product development, so too should decision makers consider the impacts on economic and scientific progress when precaution is invoked as a reason to slow or halt an activity or technology.

A strong, effective, but efficient and fair risk management system is vital in a society increasingly reliant on numerous technologies, none of which are risk free but few of which we have needed to manage by resorting to bans. The Council strongly supports OMB's efforts to comprehensively evaluate the strengths and weaknesses of the current environmental, health and safety management system and to create a system that appropriately balances precaution in managing risks with other fundamental public interests.

* * *

IV. CONCLUSION

The Council is pleased to have had the opportunity to comment on the Office of Management and Budget's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations. The Council appreciates OMB's interest and efforts in fostering accurate, balanced and cost-effective risk assessment and risk management. Although the Council fully understands that an appropriate degree of caution should be used in making risk management decisions, such caution should be applied transparently in the risk management phase, and not opaquely in the risk assessment phase. Risk assessments, for their part, must seek to provide the best and most objective estimates of risk possible, leaving policy judgments to the risk managers. If these fundamental changes are actually implemented by EPA, all sectors will benefit.

The Council hopes these comments will assist OMB and others in the Executive Office who are seeking to improve federal regulatory analysis and management. The Council looks forward to working with OMB on this and similar matters in the future.

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VI. APPENDICES

APPENDIX 1 W.Kip. Viscusi & James T. Hamilton, Are Risk Regulators Rational? Evidence from Hazardous Waste Cleanup Decisions (AEI-Brookings Institute Joint Center for Regulatory Studies, Working Paper 99-2 (April 1999)

APPENDIX 2 AMEC Earth & Environmental, Development of a Revised Chronic Reference Dose for Polychlorinated Biphenyls (Aroclor 1254) Based on Empirical Data

APPENDIX 3 AMEC Earth & Environmental, Use of a Toxic Equivalency Quotient Approach Based on 2,3,7,8-TCDD to Evaluate Potential Carcinogenic Risks of PCBs (Sept. 26, 2001)

APPENDIX 4 Table of conservative default assumptions from EPA risk methodologies

APPENDIX 5 Examples of Risk Assessments that Grossly Overstate Risk