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**U.S. House of Representatives**  
**Committee on Energy and Commerce**  
**Washington, DC 20515-6115**

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June 1, 2006

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Re: Comments on Proposed Office of Management and Budget Risk Assessment Bulletin

Dear Acting Director Johnson and Acting Director Arbuckle:

We are writing to comment on the proposed Office of Management (OMB) and Budget Risk Assessment Bulletin for Federal agencies. We applaud the OMB and the Office of Information and Regulatory Affairs for proposing these guidelines. For more than a decade Members of the Committee on Energy and Commerce have had concerns with policy bias driving Federal risk assessment. This bias is not legally permissible. The legal requirement is for Federal agencies to meet the objectivity requirement as provided in the data quality language in section 515 of the Fiscal Year 2001 Treasury, Postal Service and General Government Appropriations Act (P. L. 106-554)

We believe Federal agencies are not following this requirement. We believe the risk assessment guidance is an important step in moving forward to comply with the law. We further suggest that Federal agencies provide an implementation plan to transform their current practices into objective risk assessment practices. This would, among other things, mean that Federal agencies would need to explain the weight of the scientific evidence behind critical assumptions and provide, among a broader risk profile, central estimates supported by the weight of the scientific evidence. Anything shy of this would be a simple continuation of the practice of allowing policy to drive risk assessments. Our comments offer specific revisions for the Bulletin, following a discussion of objectivity, assumptions, transition plans, and the enforceability of the Data Quality Act.

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**Objectivity Requires that Agencies Determine which Assumptions are Supported by the Weight of the Scientific Evidence and Present Central Estimates Supported by the Weight of the Scientific Evidence .**

In the section on standards related to objectivity in the Proposed Bulletin, OMB states important principles:

“Risk assessments must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risk. On a substantive level, objectivity ensures accurate, reliable and unbiased information. When determining whether a potential hazard exists weight should be given to both positive and negative studies, in light of each study’s technical quality. The original and supporting data for the risk must be generated, and the analytical results developed, using sound statistical and research methods.”

The Proposed Bulletin also states:

“Beyond the basic objectivity standards, risk assessments subject to this Bulletin should use the best available data and should be based on the weight of the available scientific evidence.”

The Proposed Bulletin cites the Risk Commission Report at Volume 1 at page 38, which states:

“...Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.”

We applaud OMB’s statements in this area with one exception. We believe the final Bulletin should strike the notion that the weight of the evidence requirement is “beyond the basic objectivity standard.” We believe the weight of the evidence standard is inherent in an objective process. It is also inherent in determination of the best scientific information. If you are not using a weight of the evidence approach then you are applying a policy bias as a decision criteria. This would not be objective.

We offer further support for this proposition and ask that this support be mentioned in the preamble to the Bulletin. First, we note that Executive Order 12866 states:

“Each agency shall base its decision on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for and consequences of the intended regulations.”<sup>1</sup>

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<sup>1</sup> E.O. 12866, section (1)(b)(7) (emphasis added).

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The best scientific information is that with the greatest support and weight of scientific evidence. Best Practices guidelines issued during the Clinton Administration amplify on this standard:

"Risk management is an activity conceptually distinct from risk assessment.... The risk assessment should generate a credible, objective, realistic, and scientifically balanced analysis....The data, assumptions, models, and inferences used in the risk assessment to construct quantitative characterizations of the probabilities of occurrence of health, safety, or ecological effects should not reflect unstated or unsupported preferences for protecting public health and the environment, or unstated safety factors to account for uncertainty and unmeasured variability. Such procedures may introduce levels of conservatism that accumulate across assumptions and make it difficult for decision-makers to evaluate the magnitude of the risks involved."<sup>2</sup>

This language is fully consistent with related legislative mandates. For example, the Safe Drinking Water Act Amendments of 1996 (SDWA) state in part:

"[T]he Administrator shall use --- (1) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."<sup>3</sup>

The SDWA provision further states that:

"[T]he Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable --

(ii) the expected risk or central estimate of risk for the specific populations...

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data."<sup>4</sup>

The D.C. Circuit has construed the language of the SDWA to avoid policy bias:

".... The fact that EPA has arrived at a novel, even politically charged, outcome is of no significance either for its statutory obligation or for fulfillment of its adopted policy....The statute requires the agency to take into account the "best available" evidence. 42 U.S.C. § 300g-1(b)(3)(A) (emphasis added). EPA cannot reject the "best available" evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action -- a possibility that will always be present."<sup>5</sup>

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<sup>2</sup> From Office of Management and Budget Best Practices Document "Economic Analysis of Federal Regulations under Executive Order 12866" January 11, 1996.

<sup>3</sup> 42 U.S.C. 300g-1(b)(3)(A) (emphasis added).

<sup>4</sup> 42 U.S.C. 300g-1(b)(3)(B) (emphasis added).

<sup>5</sup> Chlorine Chemistry Council v. EPA 206m F. 3d 1286 (D.C. Cir. 2000).

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We note that, in addition to the SDWA standard referred to in the preamble, Congress has recently adopted a Sense of Congress that states:

"It is the sense of Congress that Federal agencies conducting assessments of risks to human health and the environment from energy technology, production, transport, transmission, distribution, storage, use, or conservation activities shall use sound and objective scientific practices in assessing such risks, shall consider the best available science (including peer reviewed studies), and shall include a description of the weight of the scientific evidence concerning such risks."<sup>6</sup>

The 1997 Recommendations of the Risk Commission support objective and unbiased assessments and the weight of the scientific evidence approach:

"A good risk management decision . . . [i]s based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment."<sup>7</sup>

"[T]he Commission's Risk Management Framework is intended to: ...[e]nsure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence."<sup>8</sup>

"Making judgments about risk on the basis of scientific information is called 'evaluating the weight of the evidence.'... It is important that risk assessors respect the objective scientific basis of risk and procedures for making inferences in the absence of adequate data."<sup>9</sup>

"Because so many judgments must be made based on limited information, it is critical that *all* reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions."<sup>10</sup>

Other organizations have also stated support for these propositions. The 1999 Recommendations of the American Bar Association Section of Administrative Law and Regulatory Practice states, in part:

"Risk assessment considers an important and useful subset of information relevant to regulatory decisions. It should provide scientific estimates and characterizations of the

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<sup>6</sup> Section 1401 of Energy Policy Act of 2005 (emphasis added)

<sup>7</sup> The Presidential/Congressional Commission on Risk Assessment and Risk Management; Framework for Environmental Health Risk Management, Final Report, Volume 1 at 4 (1997) (emphasis added).

<sup>8</sup> Id. at 5 (emphasis added).

<sup>9</sup> Id. at 23 (emphasis added).

<sup>10</sup> Id. at 38 (emphasis added).

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nature and magnitude of risks posed to human health, human safety and the integrity and quality of the environment, and should be based on careful analysis of the weight of all available evidence. The process should be constructed to avoid bias and political pressure..."

The Committee on Energy and Commerce received a statement from 20 fellows and former presidents of the Society for Risk analysis that states, in part:

"...Congress should press regulators to use the best available scientific knowledge in formulating estimates.

Risk estimates should include not only upper bound estimates but also estimates based on the best scientific understanding.... The point is that risk estimators should be pushed to use the best scientific understanding of the issues, not some arbitrarily conservative estimate based on assumptions rather than knowledge. Presenting only 'conservative' estimates leave decision-makers with no scientific basis for distinguishing which risks are real; they can lead to unnecessarily costly regulation of trivial risks, diverting attention from important public health risks."<sup>11</sup>

#### **OMB Should Clarify the Application of Objectivity and Weight of the Evidence Principles with Respect to Assumptions**

As discussed above, risk information must be based on an objective scientific process. Safety factors or measures based on assumptions designed to produce an overestimate of risk are statements of policy and not themselves scientific assessments of risk. It is important that Federal agencies maintain the distinction between true risk assessments and risk management policy measures.

In order to meet the statutory provisions for quality, objectivity, utility, and integrity of risk information, Federal agencies must present a more complete and clear package of information to the public. Best estimates based on assumptions with the greatest weight of scientific evidence are critical pieces of information to provide quality, objectivity, utility and integrity. Best estimates are important for cost-benefit analyses and for comparisons among risks. Moreover, by avoiding the decision criteria of "conservatism" such estimates carry more scientific integrity than measures that mix science and public policy. Such best estimates must be an anchor to risk assessment information presented to the public.

Accordingly, Federal agencies should, among other estimates or measures, present risk estimates or measures that are based on assumptions that have the greatest support in the weight of scientific evidence and are based on the best science. This is the baseline objective of risk assessment. Information purporting to state risks to human health or the environment should contain this information.

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<sup>11</sup> Letter from 20 fellows and former presidents of the Society for Risk Analysis, reprinted in Joint Hearing before the Subcommittee on Commerce, Trade, and Hazardous Materials and the Subcommittee on Health and Environment, February 1 and 2, 1995.

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Along with the baseline best estimate, other risk measures may be useful as indicators of uncertainty and variability. Such measures may also be useful in setting forward a screening process to determine whether further analysis is worthwhile. Moreover, choosing a given risk measure to achieve a program objective depends on the policy and legal context. Finally, nothing in our comments suggest how much evidence is necessary for regulation. But, such choices do not themselves become risk assessments or risk information. The failure to present measures reflecting the greater weight of the scientific evidence and best available science evades the Congressional mandates of quality, objectivity, utility, and integrity of information purporting to be a risk assessment.

Federal agencies should indicate their view on which assumption has the most support in view of the best available science. At least one risk measure should be produced based on the weight of the scientific evidence. When assumptions have equal support, it is acceptable to provide measures based on each such assumption. Measures should not be identified as central tendency measures where such measures are based on assumptions designed to overstate the risk.

#### **OMB Should Require Transition Plans with Enforcement Mechanisms for Agencies to Come into Compliance**

A 2001 General Accounting Office (GAO) report examined risk assessment guidance documents and procedures at EPA, the Food and Drug Administration, the Occupational Health and Safety Administration, and the Department of Transportation to determine whether the agencies stated a specific scientific or policy basis for their choices.<sup>12</sup> The GAO study demonstrated multiple problems with current practices. First, the report found gaps in agency explanations. Agency guidance did not explain the basis for significant assumptions approximately a quarter of the time. The agencies provided GAO information on the likely effects of using particular assumptions or methods in only about half of the examples. When that information was provided, it was usually in the context of whether and to what extent the agencies' choices could be considered precautionary. The agencies acknowledged that such practices can result in "multiple conservatisms" and that some of these choices are likely to overstate risk by an unknown amount. Such assessments do not provide decision-makers or the public with risk information based upon assumptions that are supported by the greater weight of scientific evidence or that rely on the best available science.

We have little reason to believe that Federal agencies are today meeting the objectivity standards of the Data Quality Act. We believe we need concrete plans to change current practice. Even in the draft preamble to the proposed Bulletin, OMB would overlook one of the major issues. In the discussion of dose-response OMB states:

"Techniques have been developed to perform such extrapolations and to portray the resulting uncertainty in risk estimates associated with the extrapolation."

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<sup>12</sup> Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies (Aug. 6, 2001 GAO-01-810).

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The linear extrapolation from mega-dosed rodents is part of the problem. Federal agencies do not provide a weight of the evidence analysis to determine which extrapolation assumption has the greatest weight of scientific evidence or whether a threshold model has greater support. The "estimates" OMB refers to are highly implausible. If these were the only numbers provided, we do not believe such estimates on their own would meet the objectivity standard. Federal agencies merely give this implausible number and declare it a conservative estimate. But how scientifically plausible and how conservative is the linear extrapolation model? We hardly believe agencies are accurately portraying the resulting uncertainty by simply declaring it a conservative estimate. The numbers some Federal agencies provide in this manner have no scientific meaning. The choice of the linear extrapolation model is the result of a policy decision to be conservative, not a statement of the weight of scientific evidence. The resulting numbers only reflect a determination of management policy and not of science. OMB must demand determinations based on science and not policy.

There are a number of steps that can be taken quickly and these should be emphasized. For example, historically agencies have selected values based on 95% of the distribution curve for certain assumptions. These are then placed into risk assessment algorithms that compound the choices of a 95% assumption several times over. Given the current abilities in software and statistics, there is no reason to continue such a practice. The appropriate method is to input the entire distribution curve into the algorithms. Federal agencies can move forward on this by getting statisticians and software designers to revisit current risk assessment algorithms to make this change. This requires leadership and willpower.

We suggest that OMB set out a plan of action to move Federal risk assessment practice to the standard of objectivity.

### **The Standards of the Data Quality Act are Enforceable as Provisions of Law**

Section XI states that the Bulletin is intended to improve internal management of the Executive Branch and is not intended to create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person. Accordingly, if a rulemaking relies on a risk assessment that does not meet the standards of P.L. 106-554 such a rulemaking is not consistent with law. This would be similar to the decision in *Chlorine Chemistry Council v. EPA* 206m F. 3d 1286 (D.C. Cir. 2000). Other risk assessments may also qualify for judicial review. We would also note the principle that agencies follow Federal guidance or be found to have taken action that is arbitrary and capricious. We believe most of the statements of the Bulletin are part of OMB's responsibilities under the Data Quality Act. Thus, the statement in Section XI should not operate as a shield for determinations by courts of what is consistent with law.

### **Specific Revisions to the Proposed Risk Assessment Bulletin are Necessary**

In order to comply with the objectivity standard and consistent with our above comments and references, we request the Risk Assessment Bulletin reflect the following changes.

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### Applicability

Under the provision styled the section on Applicability, the proposed bulletin states--

"To the extent appropriate, all agency risk assessments available to the public shall comply with the standards of this Bulletin."

We question the need for the "to the extent appropriate." This clause seems to suggest that compliance with the Bulletin is discretionary with agencies. We are unclear under what circumstances OMB considers compliance with the bulletin "inappropriate." If there must be a qualifier, the lead in should say, "Unless otherwise determined by the Office of Management and Budget as inappropriate under special circumstances...." Under the Data Quality Act, it is the duty of OMB to ensure objectivity.

### Goals

Our concern on the Goals section is similar to our concern on applicability. We do not want the Statement of Goals to suggest that compliance with other provisions of the Bulletin is not necessary. For example the Goals state:

"The scope and content of the risk assessment shall be based on the objectives of the assessment..."

We do not believe the requirements for objectivity or presentation of information should be undermined by an agency's determination of the "objectives of the assessment." Accordingly, we recommend stating as a lead in for the Goals section:

"In addition to the other requirements of this Bulletin --"

### General Risk Assessment and Reporting Standards

Consistent with our discussion that objectivity requires determination and use of those assumptions that are supported by the greatest weight of scientific evidence, we suggest the following changes in this section as indicated by bold and italicized language:

3. Provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates shall be provided, ***including estimates based on the weight of the scientific evidence.***

4. Be scientifically objective:

( ) ***Determine assumptions and estimates with the most weight of the scientific evidence;***



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5. For critical assumptions in the assessment, whenever possible, include a quantitative evaluation of reasonable alternative assumptions, *including assumptions supported by the greatest weight of scientific evidence*, and their implications for the key findings of the assessment.

7. For risk assessments that will be used for regulatory analysis, the risk assessment also shall include:

(e). whenever possible, a range of plausible risk estimates, including central or expected estimates *based on the weight of scientific evidence*, when a quantitative characterization of risk is made available.

**Special Standards for Influential Risk Assessments**


Finally, our suggestion here is consistent with our prior comments:

3. Highlight central estimates *based on the weight of scientific evidence*, as well as high-end and low-end estimates of risk when such estimates are uncertain.

Again, we support and applaud the effort to infuse science and objectivity into decision making. We offer our comments in an effort to improve the direction of the Bulletin and hope they will be given every consideration. If you have any questions, please contact Nandan Kenkeremath of the Committee on Energy and Commerce staff at (202) 225-2927.

Sincerely,

  
Joe Barton  
Chairman

  
Paul E. Gillmor  
Chairman  
Subcommittee on Environment  
and Hazardous Materials

cc: Ambassador Robert J. Portman, U.S. Trade Representative