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UNITED STATES OF AMERICA

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May 18, 2006

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
727 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The U.S. Chamber of Commerce (U.S. Chamber) is pleased to send you this letter in response to the call for comments concerning[1] the Office of Management and Budget (OMB) *Proposed Risk Assessment Bulletin* (Bulletin). The U.S. Chamber is the world's largest business federation representing more than three million businesses and organizations of every size, sector, and region.

Many of the U.S. Chamber's members are either engaged in activities involving the use of risk assessments or are impacted by the assessments. In addition, as the U.S. Chamber and others have demonstrated[2], poorly characterized information used to perform risk assessments can have a wide-ranging, adverse impact on risk management decisions, leading to instances in which business and industry can be forced by regulators to unnecessarily expend many tens of millions of dollars in clean-up actions and other remedial activities. As such, the U.S. Chamber welcomes and applauds this undertaking by OMB to improve the risk assessments performed by federal government agencies and especially in requiring a

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[1] Office of Management and Budget, *Proposed Risk Assessment Bulletin*, Washington, DC, January 9, 2006; found at: http://www.whitehouse.gov/omb/pubpress/2006/2006-01.pdf, accessed March 15, 2006.

[2] See U.S. Chamber of Commerce, Request for Correction of Data in Databases and Models Disseminated by EPA (RFC 04019), May 26, 2004 and U.S. Chamber of Commerce, Request for Reconsideration of RFC 04019 (RFR 04019A) at http://www.epa.gov/quality/informationguidelines/iqg-list.html; I. Linkov, et al, "Uncertainty in Octanol-Water Partition Coefficient: Implications for Risk Assessment and Remedial Costs" *Environmental Science & Technology* **39**(18), 6917-6922, 2005; J. Pontilillo and R. Eganhouse, *The Search for Reliable Aqueous Solubility (S_w) and Octanol-Walter Partition Coefficient (K_{ow}) Data for Hydrophobic Organic Compounds: DDT and DDE as a Case Study*, Water-Resources Investigations Report 01-4201, U.S. Geological Survey, Reston, VA 2001; [http://pubs.usgs.gov/wri/wri014201/]; Urs Schenker, Matthew Macleod, Martin Scheringer, and Konrad Hungerbühler, "Improving Data Quality for Environmental Fate Models: A Least-Squares Adjustment Procedure for Harmonizing Physicochemical Properties of Organic Compounds" *Environmental Science & Technology* **39**(21), 8434–8441 (2005); and Dale Marino, "Variability in Physical Constant Parameter Values from Standard Data Sources and the Implication of this Variability for Risk Analysis" *Risk Analysis* **26**(1), 185-201 (2006).

reliable characterization of the uncertainties that impact the quality and useful information content of the assessments. Simply put, failure to get risk driven regulatory policy correct, in the aggregate, can result in the unnecessary expenditure of billions of dollars and pronounced regulatory inefficiencies—having to expend more resources, labor, and capital to address a problem than is necessary means that less resources are available to address other problems.

In large measure, the U.S. Chamber concurs with the text of the Bulletin, and strongly encourages that the recommended actions to improve risk assessments, their use, and communications about them be implemented. As set out below, the U.S. Chamber offers some comments and observations that OMB may find helpful in strengthening the Bulletin as well as improving its usefulness and clarity.

The organization of these comments is as follows. "General Observations" and "Specific Observations" concerning the OMB Bulletin are included in the body of this letter. Additional, supplemental information is annexed to this letter and consists of two additional sections of text, respectively labeled "Supplemental Observations" and "Remarks concerning the formal language portion of the OMB Bulletin". All of this material constitute the comments submitted in response to OMB's call for public comments concerning the Bulletin.

As many of the issues raised in these comments are of a substantive nature, and if addressed, likely will lead to extensive revision of the Bulletin, the U.S. Chamber recommends that such a revised Bulletin be reissued for a second round of public review and comment.

Ahead of the discussion provided below in these comments, one point, however, is in the U.S. Chamber's judgment of such particular importance that it merits noting at this juncture. Specifically, the apparent lack of judicial review is a significant weakness.[3] This begs the question of what happens if agencies simply choose to ignore the directions given in the OMB Bulletin. If this situation arises, what measures will OMB undertake to ensure that the agencies follow the instructions set out in the Bulletin? Unfortunately, it appears that the information provided in the document lacks clarity on this very important matter.

This is a situation that deserves serious scrutiny, for in the U.S. Chamber's opinion, it would be an egregious public disservice not to assure that reliable risk assessment information, as set out in the Bulletin, are established and publicly disseminated. OMB is encouraged to consider this matter carefully.

[3] See §XI. Judicial Review: "This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not 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" Footnote 1, *Ibid.*

General observations

With regard to evaluating whether a potential hazard exists and its extent of possible risk to human health, safety, or the environment, OMB has compiled and documented a persuasive body of sound scientific evidence [4] in its Bulletin that strongly suggests:

- Risk estimates must and can be improved, inclusive of more fully accounting for the uncertainty[5], nature, limitations, value, purpose, and benefits of risk estimates; on this matter, there is long-standing, well-documented, general agreement within the scientific community.
- To enable policy makers to better understand the pros and cons of regulatory options, the applicability, limitations, reliability, and ramifications of risk assessments must be more clearly communicated to them by risk assessors.
- Risk assessments must be improved to the extent that they are of sufficient transparency and utility that risk communicators can readily use them to explain to the public in clear and understandable terms why selected regulatory options based on them are optimally beneficial to accomplishing human and environmental health protection objectives.[6]

Given these circumstances and observations, the U.S. Chamber applauds OMB for undertaking its *Proposed Risk Assessment Bulletin* initiative at this time. Together with improvements realized through consideration of stakeholder comments and peer review by the National Academy of Sciences, implementation of the Bulletin provides a major opportunity to strengthen the value of risk estimates used by government agencies for regulatory purposes. Carnegie Mellon University Professor Granger Morgan, who chairs EPA's Science Advisory Board, has commented about the OMB Bulletin that:[7]

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[4] Footnote 1, *Ibid.*

[5] To appreciate the significance of uncertainties, consider the following example, which relates to regulatory impact analyses (RIAs): "Introducing uncertainties into RIAs is an important activity for at least two reasons. The first is that public policy will be better served. If uncertainties are not considered, then the resulting policy choices may fail to meet internal (but often unstated) agency criteria—or even the public's criteria—for choosing the best policy amidst high uncertainty. The second reason is more political in nature. Sole reliance on point estimates masks the underlying distribution of benefit and cost estimates, thereby giving a false sense of security to decisionmakers and the public. If the policy turns out to be a poor choice, then people may well look to the RIA to determine whether the agency had predicted the possibility of such an outcome. To avoid being blindsided, decisionmakers can build uncertainties into their ex ante analyses." As noted in: A. Krupnick et al., *Not a Sure Thing: Making Regulatory Choices Under Uncertainty*, Resources For the Future, Washington, DC, 2006, accessed at: http://www.rff.org/rff/News/Features/Not-a-Sure-Thing.cfm?.

[6] "…better and more complete information does not necessarily lead to better policies. Complex information can confound rather than enlighten or can paralyze the decisionmaking process. Thus, any improvements in capturing uncertainty analytically must be matched by improvements in its communication—not only to those who make regulatory decisions on the basis of such information but also to stakeholders, judges, the press, and the general public." *Ibid.*

[7] In: J. Kaiser, "More Details Sought in Assessing Health Risks" *Science*, Vol. 311, p. 161, January 13, 2006.

This outlines things agencies should have been doing all along.

Kimberly Thompson of Cambridge-based Massachusetts Institute of Technology and president-elect of the Society for Risk Analysis similarly[8] applauds the greater emphasis on quantitative tools. The U.S. Chamber is in complete concurrence with their expressed views.

Specific observations

Problems with disclaimers

OMB instructs that:[9]

…it is expected that every risk assessment (even screening-level assessments) will comply with other standards in Section IV[10]

The U.S. Chamber recommends that OMB require that agencies not seek to circumvent this expectation through use of various disclaimers. For example, EPA denies responsibility for assuring the quality of data, databases, and models such as are used in support of risk assessments when this information is issued by third parties despite the fact that EPA recommends, disseminates, or sponsors the dissemination of such data, databases, and models. It justifies this by noting either that copyright is held by the third party, that the data, databases, or models are proprietary, or that the information was not developed by EPA. Often, however, such information has been developed in whole or part with federal government funds that were provided to the third party by EPA, as for example, has been the case (ongoing) concerning development of the EPI Suite.[11] As another example, EPA's Water9 package includes an extensive disclaimer in the initial pop-up window, which reads as follows:

This software and the accompanying files are provided as is and without warranties as to the performance or merchantability or any other warranties whether expressed or implied. The user assumes the entire risk of using the program.

Similarly, EPA's Human Health Risk Assessment Protocol Companion Database (HHRAP) contains the following disclaimer:

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[8] *Ibid.*
[9] See p. 9 of Bulletin in Section II: Applicability, Footnote 1, *Ibid.*
[10] NB: with the exception of screening-level standards not having to meet the standard of neither minimizing nor exaggerating the nature and magnitude of risk.
[11] As confirmed in materials received January 31, 2006 from EPA in response to the U.S. Chamber's Freedom of Information Act Requests HQ-RIN-00829-05 and HQ-RIN-01081-05.

Neither the United States Government nor any agency thereof, nor any of their employees or officials, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe on privately owned rights.

It is interesting to note that before users are permitted by EPA to access and use the HHRAP database, they must first click on a button that reads "I agree".[12] These strictures would seem contrary to the intent of OMB to improve the risk assessment process.

The Chamber surmises that the user might be held responsible for any errors in risk assessment using these agency disseminations if there was a regulatory compliance issue, as EPA has issued this warning and cautionary statement. This position would seem on its face to negate the spirit of both the Bulletin as well as the Data Quality Act.

EPA also sometimes denies responsibility for correcting risk assessment related data on the basis of its argument that new databases and models have superseded previously distributed models. But doing this neglects the fact that errors can propagate from one database and model to another. There is also an implicit waiver of responsibility in many models and databases used for risk assessments that EPA disseminates or whose dissemination it sponsors or recommends, in that EPA fails to provide any cautionary statements that data are in error and it fails to provide reasonable discussions of data uncertainty; the Agency has in effect waived its responsibility to perform this task, despite the fact that it is a reasonable, and near universal expectation of scientists and engineers that information should be qualified in terms of the certainty (or uncertainty) with which it is known.

Moreover, in making blanket statements that databases and models used in support of risk assessments are in conformance with OMB and agency Information Quality Guidelines, without explaining why such a statement is valid—for example, as is done in the case of the HHRAP package disclaimer/agreement, EPA fails to acknowledge its responsibility to provide transparency in its reasoning concerning data quality related to risk assessments. The Agency also denies responsibility to correct data errors by stating patently false facts, such as assertion of the robustness of peer reviews of contentious, risk related information.[13]

Another noteworthy issue is entries at EPA's *The Inland Testing Manual*[14] (Full text) (Index of PDF documents, by chapter title)—where "Full text" is a link, and "Index of PDF

[12] The disclaimer/agreement is accessed through the following EPA web site: http://www.epa.gov/epaoswer/hazwaste/combust/risk.htm.

[13] For example, the U.S. Chamber finds that EPA [EPA response to Chamber FOIA HQ-RIN-00847-05, March 31, 2005] has no record of any peer review of its CHEMFATE package; See also the text of the U.S. Chamber's Request for Reconsideration of its Request for Correction, Footnote 2, *Ibid.*

[14] See http://www.epa.gov/waterscience/itm/.

documents, by chapter title" is a link. If a person clicks on the link for "Full text" a disclaimer is found. If, instead one clicks on the link to the "Index of PDF documents, by chapter title", a disclaimer is not found. Unfortunately, as a further complication, none of this is relevant if one instead finds the document by "Googling" for it and downloading it directly—in this case one will never know about any disclaimer that may or may not exist. This observation argues that disclaimers, if acceptable at all, should be present in the documents, and not on web sites.

Risk assessors

OMB instructs that:[15]

> *... risk assessors should engage in an iterative dialogue with the agency decision maker(s) who will use the assessment.*

Perhaps it would be helpful to clarify that "risk assessors" encompasses more than just those in the employ of the particular agency wherein decision maker(s) are addressing a particular issue. For example, some risk assessment issues cross-cut the activities of several government agencies, such as assessments of health and environmental risks associated with the presence of mercury in the environment. In such instances, decision maker(s) at one agency may want to more broadly confer with risk assessors at any one of several agencies to gain insight into a risk assessment matter. OMB should encourage agency decision maker(s) to seek the advice of risk assessors throughout the federal government (and perhaps elsewhere) in instances where it would be prudent to do this.

Weight of evidence

OMB instructs that:[16]

> *… 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 requirement for using the best available scientific evidence was applied by Congress*[17] *to risk information…*

The U.S. Chamber suggests that for clarity and to remove any ambiguity, the above text should be revised as follows:

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[15] See p. 10 of Bulletin in Section III: General Risk Assessment and Reporting Standards, Subsection 1–Goals Related to Problem Formulation, Footnote 1, *Ibid.*

[16] See p. 14 of Bulletin in Section IV: General Risk Assessment and Reporting Standards, Subsection 4–Standards Related to Objectivity, Footnote 1, *Ibid.*

[17] Refer to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A)&(B) and Footnote 16, *Ibid.*

> *… risk assessments subject to this Bulletin should use the best available data and should be based on the weight of the* ***best*** *available scientific evidence. The requirement for using the best available scientific evidence was applied by Congress to risk information…*

As the Presidential/Congressional Commission on Risk Assessment and Risk Management[18] observes:

> *Because so many judgments must be based on limited information, it is critical that all* ***reliable*** [emphasis added] *information be considered.*

Thus, the clear intention is that risk assessments—inclusive of weight of evidence considerations—should concentrate on reliable information, as opposed to any and all information, regardless of its quality.

Public access to underlying data

OMB instructs that:[19]

> *The agency also must identify the sources of the underlying information (consistent with confidentiality protections) and the supporting data and models, so that the public can judge for itself whether there may be some reason to question objectivity. Data should be accurately documented, and error sources affecting data quality should be identified and disclosed to users.*

The U.S. Chamber is concerned that the use of disclaimers (see discussion above in "Problems with disclaimers") will enable agencies to opt out of the responsibility to accurately document data and error sources affecting data quality. OMB should amplify its discussion to clarify that use of disclaimers is not a reasonable option.

Moreover, in instances in which there are alternative and reliable *non*-proprietary/*non*-confidential data and models that are comparable in reliability to proprietary/confidential data and models, OMB should require agencies to preferentially use the *non*-proprietary/*non*-confidential data and models. Failure to insist on this requirement confounds the ability of the public to access information needed to make judgments about agency risk assessment activities. When there is no recourse (i.e., no other options) to agencies having to use proprietary/confidential data and models in performing risk assessments, OMB should require the agencies in these instances to certify that such proprietary/confidential data and models are robust and reliable for the circumstances in which they are used and that such proprietary/confidential data and models have been subject to reliable scientific peer reviews applicable to the given circumstances for which this

[18] Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making,* Vol. 2, 1997,
[19] See p. 14 of Bulletin in Section IV: General Risk Assessment and Reporting Standards, Subsection 4–Standards Related to Objectivity, Footnote 1, *Ibid.*

proprietary/confidential data and model information is used. Moreover, if such peer reviews do not cover the applicable circumstances, then the proprietary/confidential data and models should not be considered peer reviewed for the intended use.

In sum, every possible effort should be undertaken to assure that agencies make accessible to the public all underlying data and models used in performing risk assessments. Generally, the public should have, to the maximum extent practical, access to all information used in developing regulations, including, but not limited to assumptions used, areas of uncertainty, populations intended for protection, and exposure assessment models. The U.S. Chamber encourages OMB to facilitate this outcome. It is imperative that this be done to maximize the ability of the public to substantially reproduce risk assessment results.

Improving public understanding of risk assessments

OMB instructs that:[20]

> *The executive summary should also place the estimates of risk in context/perspective with other risks familiar to the target audience.*

For the reasons discussed below, the U.S. Chamber suggests that the above text be edited to read as follows:

> *In a manner that is transparent and readily understandable, the executive summary should also prioritize and place the estimates of risk in context/perspective with other risks familiar both to the target audience and to the public.*

Risk assessments must be put into a context that the public can readily understand. This is important, for as EPA has noted,[21] the environmental risks that the public frequently sees to be of greatest concern often are not ranked as the greatest risks of concern by agency managers and scientists. In other words, when it comes to understanding what is a serious risk and what is not, there is a fundamental disconnect between what EPA knows and what the public perceives.

What this finding clearly indicates is that the true nature of risks is not being satisfactorily communicated to the public by government agency officials in a transparent manner. Simply put, government agencies have failed to communicate and explain in a readily understood manner what really are the risks that ought to be of greatest concern and what ought not to be given priority attention. This is a serious public disservice. Government agencies can and should be expected to do better.

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[20] See p. 21 of Bulletin in Section IV: General Risk Assessment and Reporting Standards, in Subsection 6–Standards Related to the Executive Summary, Footnote 1, *Ibid.*

[21] U.S. Environmental Protection Agency, *Unfinished Business: A Comparative Assessment of Environmental Protection*, Washington, DC, 1987.

Without a credible presentation of information that compares a specific risk of concern to everyday risks that the public well understands, the public cannot be expected to develop an informed understanding of what is reasonably of concern and what is not of concern. At a minimum, notwithstanding statutory limitations, government agencies must make an effort to better educate the public about what is known about risks.

In support of this observation, EPA's own Science Advisory Board has recommended that risks be compared and prioritized and that the highest level of attention be given to those risks that are greatest.[22] By providing comparative risk assessments that relate risks of concern to readily understood risks, the rank ordering of risk priorities by federal government officials can be better understood by the public. Doing this is not too much to ask, and the U.S. Chamber suggests that OMB, in the interest of better serving the public interest, require that all federal government agencies make such risk comparisons and rank the relative risks of interest according to a publicly understandable basis for their prioritization.[23] Absent this action, the public will not be able to understand whether environmental protection or whether (oft-times limited) funds aimed at reducing risks are being expended wisely.

Central estimates

OMB instructs that:[24]

> *When a quantitative characterization of risk is made available, this should include a range of plausible risk estimates, including central estimates. … The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the pubic with the expected risk.*

The U.S. Chamber fully concurs with this requirement and applauds OMB for making this statement, which also comports with findings of the National Research Council[25] as well as the Carnegie Commission on Science, Technology and Government, which finds that:[26]

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[22] U.S. Environmental Protection Agency, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, Science Advisory Board, Washington, DC, 1990.
[23] The concept of performing comparative risk assessments for priority setting purposes is well documented; see for example; Davies, J.C. (Ed.) *Comparing Environmental Risks: Tools for Setting Government Priorities*, Resources For the Future, Washington, DC, 1996; Minard, R. *State Comparative Risk Projects: A Force for Change*, Northeast Center for Comparative Risk, South Royalton, Vermont, March, 1993.
[24] See p. 16 of Bulletin in Section IV: General Risk Assessment and Reporting Standards, Paragraph (5) of Subsection 7–Standards Related to Regulatory Analysis, Footnote 1, *Ibid.*
[25] National Research Council, *Science and Judgment in Risk Assessment,* at 170-175, Washington, DC, National Academy Press, 1994; NB: for additional information about risk characterization, refer also to (especially pp 222-230): A. Krupnick et al, *Not a Sure Thing: Making Regulatory Choices Under Uncertainty,* Resources For the Future, Washington, DC, February 2006, available at: http://www.rff.org/rff/News/Features/Not-a-Sure-Thing.cfm.
[26] Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making*, New York, NY, June 1993; p. 87.

Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates.

The likely costs of contemplated regulatory requirements can frequently be characterized with a much lesser degree of uncertainty than the uncertainty that surrounds benefit estimates. By emphasizing the importance of unbiased, central risk estimates as an input, the reliability of benefit-cost analyses could be significantly strengthened, as proceeding in this manner would recognize and take account of the disparity in uncertainty surrounding estimates of costs and estimates of benefits.

Professional judgment

There are numerous mentions of the use of "professional judgment" in the Bulletin and literature cites therein. This concept of "professional judgment" bears more attention. There is a critical nexus between sound science information and regulatory policy and decisions. Resort to the use of "professional judgment"—a poorly defined concept if ever there was one—in establishing the basis or justification for regulation and policy is no excuse for failing to maximize the quality of a risk assessment, inclusive, for example, of all underlying assumptions, data, and models. Simply put, professional judgment does not take place in a vacuum**.**

It is remarkable therefore that, while, for example, EPA in its "professional judgment" finds that its databases and models used in performing risk assessments are in conformance with Information Quality Guidelines,[27] simple, straightforward inspection by other groups[28] has easily been able to uncover serious flaws in the peer review of the databases and models. Moreover, not only are some peer reviews flawed, in some instances, EPA never even conducted a peer review of some databases that it disseminates or whose dissemination it sponsors or recommends for use in performing risk assessments.[29]

The entire notion of how one goes about forming a professional judgment is called into question given lapses in analysis and unnecessarily strict controls on basic information relevant to risk assessment aimed at protection of public health and the environment. Taken as a whole, unqualified, non-transparent use by agencies of "professional judgment" as a

[27] For example, in its January 12, 2005 response to the U.S. Chamber's correction request (see cite in Footnote 2), EPA stated, without any explanation, that: "EPA has reviewed your RFC and determined that the existing EPA databases and models referred to in your RFC individually are in conformance with the EPA Information Quality Guidelines."
[28] See Footnote 2, *Ibid.*
[29] See Footnote 13, *Ibid.*

basis for making risk related determinations should be avoided. It leaves the public with no real way to adequately evaluate the reliability of the deliberations leading up to conclusions affecting risk assessment outcomes.

Other concerns about the use of professional judgment are also testimony to the need for OMB to clarify this concept in less ambiguous terms. For example, one way in which a professional judgment is often established is through a process of "expert elicitation." In simple outline terms, this involves describing an issue to a group of experts, providing them with available information about the issue, and eliciting through a series of queries their individual views on key aspects of the issue.[30]

Problematically, this expert elicitation approach has significant pitfalls, which must be taken into consideration; however, it is not unusual for this necessity to be overlooked. As one illustration, a select group of experts were called to testify at a Senate hearing held this spring[31] to address the use of a mandatory emissions control regime for tackling climate change. What was problematical about the use of expert judgment in that instance was that the discussion of how to address climate change through legislative initiative was, from the start, "boxed in" to consideration of mandatory controls, thereby marginalizing the possibility for any in-depth discussion of possible alternative approaches. Second, by far the majority predisposition of the experts whose opinions the Senate committee sought was favorable to the use of mandatory controls, further biasing the expert judgment process. And third, the questions posed concerning climate change ahead of the Senate hearing were exclusively focused on the design of a mandatory emissions control system, again marginalizing consideration of alternative approaches.

What the above example illustrates is that when it comes to eliciting expert judgment, it is possible to game the system by: [1] framing the issue to be discussed; [2] selecting experts whose views are predisposed; and [3] limiting discussion to consideration of questions that predispose the consideration of the issue to a specific focus. To avoid such pitfalls OMB should carefully consider what advice to provide to agencies that rely on professional judgment.

If anything, these example shortcomings point directly to the fallacy of "professional judgment" as a means to inform regulatory and policy decisions in instances where no one really has a good idea of what is meant by or what constitutes "professional judgment". Unqualified professional judgment is no excuse for failing to attend to poor quality information.

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[30] To gain a more in-depth appreciation of the complexities of this process, readers are referred to the March 13-14, 2006 Resources For the Future (RFF) workshop: "Expert Judgment: Promises and Pitfalls," details of which can be found at: http://www.rff.org/rff/Events/Expert-Judgment-Workshop.cfm . Various instructive PowerPoint presentations concerning expert judgment can be downloaded through links provided at this web site.

[31] The hearing on a mandatory control regime for limiting greenhouse gas emissions was held before the Senate Energy and Natural Resources Committee, April 4, 2006.

The U.S. Chamber strongly urges OMB to give serious further attention to this very important matter. For the sake of best serving the public interest, it is crucial that a more transparent and equitable development of the nature, justification, and applicability of "professional judgment" be established.

Multiple assessments

OMB observes:[32]

> *When risk assessors face model uncertainty, they need to document and disclose the nature and degree of model uncertainty. This can be done by performing multiple assessments with different models and reporting the extent of the differences in results. A weighted average of results from alternative models based on expert weightings may also be informative.*

The U.S. Chamber applauds OMB for pointing out that model uncertainty can be a significant issue and for suggesting means to address this issue. As OMB notes in its Bulletin, numerous ways to address and assess model uncertainty are available.

In addition to the citations provided by OMB to literature that relates to this matter, mention should also be made of a recent publication[33] produced by Resources For the Future, *Not a Sure Thing: Making Regulatory Choices Under Uncertainty*, which examines and contrasts a number of approaches and methods for addressing modeling uncertainty. The U.S. Chamber also notes the growing use of the Bayesian model averaging approach, described, for example, in peer-reviewed research[34] reported by Gary Koop and Lise Tole who note that:[35]

> *By neglecting the issue of model uncertainty—or which models, among the myriad of possible models researchers should choose from to estimate health effects—most studies overstate confidence in their chosen model and underestimate the evidence from other models, thereby greatly enhancing the risk of obtaining uncertain and inaccurate results.*

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[32] See p. 18 of Bulletin in Section V: General Risk Assessment and Reporting Standards, Subsection 4–Standards for Characterizing Uncertainty, Footnote 1, *Ibid.*

[33] A. Krupnick et al, *Not a Sure Thing: Making Regulatory Choices Under Uncertainty,* Resources For the Future, Washington, DC, February 2006 at: http://www.rff.org/rff/News/Features/Not-a-Sure-Thing.cfm.

[34] G. Koop and L. Tole. "Measuring the health effects of air pollution: to what extent can we really say that people are dying from bad air?" *Journal of Environmental Economics and Management*, Vol. 47, 2004, pp. 30-54; Also, for a brief discussion of the significance and power of the Bayesian model averaging technique as used by Koop and Tole, refer to: R. McKitrick, "Smog Deaths: 0" *Financial Post*, Thursday, February 5, 2004.

[35] The authors report that: "This paper discusses the importance of model uncertainty for accurate estimation of the health effects of air pollution and demonstrates its implications in an exercise that models pollution-mortality impacts using a new and comprehensive data set for Toronto, Canada. The main empirical finding of the paper is that standard deviations for air pollution-mortality impacts become so large as to question the plausibility of previously measured links between air pollution and mortality." *Ibid.*

Adverse effects

OMB observes:[36]

> *In chemical risk assessment, for example, measuring the concentration of a chemical metabolite in a target tissue of the body is not a demonstration of an adverse effect, though it may be a valid indicator of chemical exposure. Even the measurement of a biological event in the human body resulting from exposure to a specific chemical may not be a demonstration of an adverse effect. Adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges.*

There will no doubt be considerable on-going discussion of this point about adversity that OMB has raised. The U.S. Chamber suggests that, at a minimum, the specific text noted above should be qualified by inclusion of supporting reference cites to the peer reviewed scientific literature. Examples—by way of citing such scientific literature references—of how this point has come into play in previously reported risk assessments would be instructive. What happens if one agency says a particular adverse effect in fact occurs, while given the same information, another agency disagrees? How can this matter be satisfactorily resolved?

Certification

OMB observes:[37]

> *For each risk assessment subject to this Bulletin, the agency shall include a certification, as part of the risk assessment document, explaining that the agency has complied with the requirements of this Bulletin and the applicable Information Quality Guidelines, except as provided in Section VIII [Deferral and Waiver].*

One question that arises is: Who is to be the designated certification officer of an agency? A second question that arises is: What consequences will arise if a false or incorrect certification is filed? A third question that arises is: How will a false or incorrect certification be detected? A fourth question that arises is: Will the public have access to the certifications and underlying documentation? Finally, what remedies are possible?

These are important questions, for example, in recent testimony[38] to the House Committee on Government Reform, the U.S. Chamber noted that:

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[36] See p. 20 of Bulletin in Section V: General Risk Assessment and Reporting Standards, Subsection 4–Standards for Characterizing Human Health Effects, Footnote 1, *Ibid.*
[37] See p. 21 of Bulletin in Section VII: Certification, Footnote 1, *Ibid.*
[38] Statement of William l. Kovacs, Vice president U.S. Chamber of Commerce Before the Committee on Government Reform, Subcommittee on Regulatory Affairs, U.S. House of Representatives on the subject of the Paperwork Reduction Act at 25: Opportunities to strengthen and improve the law, March 8, 2006

According to a recent study[39] by the Government Accountability Office (GAO), federal agency Chief Information Officers (CIO) had certified that Paperwork Reduction Act (PRA) standards were met in 98% of that year's 8,211 Information Collection Requests (ICR). Yet, when the GAO randomly sampled these ICRs it found that support for that certification was missing or inadequate in 65% of the cases. The reason for this shocking disparity was clear—CIO's were not analyzing the underlying documentation to ensure burden reduction standards were being met. But why should agency CIO's take the time and effort to ensure the integrity of the certification process? After all, there are no penalties for not doing so. The current CIO review and certification process required under the 1995 amendments is broken because the PRA lacks any enforcement mechanism or penalty provisions for noncompliance. As such, the certification process is an ineffective tool for verifying paperwork burden reductions. In order to rectify this problem there needs to be an enforceable penalty provision in the PRA for unsubstantiated certifications. If U.S. businesses can be held strictly accountable for recordkeeping and reporting requirements under a vast array of laws and regulations, then the federal government should be held to the same certification standards.

The possibility should not be discounted that similar circumstances could arise without further clarifying language concerning Certifications in OMB's Bulletin. It is especially important that transparency of process be assured, or the public will lack confidence in the process.

Deferral and Waiver

OMB observes:[40]

The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale.

Questions that arise in regard to this statement are as follows. Can the agency head delegate waiver authority to one or more subservient agency officials? Under what circumstances and for how long? Must each and every specific risk assessment that an agency wants waived, be waived on an individual, case-specific basis, or can there be some form of collective, sectoral, categorical, or other form of blanket or more encompassing waiver be granted? What are the pros and cons, and again, for how long? What if the subject risk assessment exercise is an *interagency* undertaking and there are conflicts of opinion among the agencies as to what should or should not be waived? Moreover, will the public be able to have access to or examine the waiver statements in any or all instances in which waivers are sought? What about access to the underlying documentation produced in support of the

[39] "Paperwork Reduction Act: Burden Reduction May Require a New Approach," Testimony Before the Subcommittee on Regulatory Affairs, Committee on Government Reform, House of Representatives, GAO, June 14, 2005.
[40] See p. 22 of Bulletin in Section VIII: Deferral and Waiver, Footnote 1, *Ibid.*

waiver? The U.S. Chamber suggests that OMB might want to consider ways in which to clarify these matters.

The U.S. Chamber appreciates this opportunity to comment on OMB's Proposed Risk Assessment Bulletin. Thank you for your attention to the matters raised in these comments. The U.S. Chamber considers a cost-effective, efficient, open, and transparent regulatory process to be a fundamental obligation of all federal agencies. Improvements in risk assessments used for regulatory purposes support realization of this outcome. Please feel free to contact me if you have any questions or require additional information.

Sincerely,

William L. Kovacs

Encl: Supplemental Information

SUPPLEMENTAL INFORMATION

Supplemental observations

Ecological and other risks

Notwithstanding various references to ecological concerns in cited literature references, the OMB Bulletin appears mainly concerned with giving advice concerning the assessment of *human* health risks. The U.S. Chamber recommends that much more explicit attention and direction be given toward assessment of ecological risks, especially as many stakeholders have either voiced concerns about the assessment of ecological risks or are impacted by regulatory decisions related to ecological endpoints, such as in regard to assessment of natural resource damages or in regard to permitting of business operations. [NB: this latter issue is also impinged upon as regards risks arising from the nature of project engineering objectives.]

At a minimum, OMB should consider making clear that its expectations for the quality of human health risk assessments apply as well to considerations of other types of risks (e.g., ecological, engineering). Indirect allusions to expectations concerning other types of risks leaves many questions unanswered or ambiguous in their resolution and as such does not serve the public interest. OMB may want to perhaps consider amplifying its expectations in regard to other types of risks by way of giving some concrete examples of applications.

Coordination

Coordination of both intra- and inter-governmental agency risk assessment activities should be effected to assure harmonization of approaches as well as stakeholder equity. As one example[1] of discordance that has arisen, various EPA regions have in the past carried out risk assessments of trichloroethylene (TCE) contamination such that substantial differences in calculated risks from the same level of TCE exposure were apparent across the United States as determined by the different EPA regional offices. OMB should carefully consider the merits of and how to assure improved coordination and harmonization of diverse agency risk assessment procedures.

Training

OMB may want to consider asking agencies to develop peer-reviewed training manuals for the education and benefit of staff and government contractors who are or will be engaged in performing risk assessments. Perhaps it may also be prudent to establish a risk assessment training course which would be taken by such staff, and to whom will be given a

[1] A. Nye, Center for Toxicology and Environmental Health, L.L.C., Comments concerning the OMB Proposed Risk Assessment Bulletin, March 10, 2006.

certificate of training completion on satisfactorily passage of the course. One question that arises is as to whether there may be benefits to encouraging inter-agency development of the materials, coursework, and certification requirements. Such measures may give the public a heightened measure of confidence in the risk assessment activities of the various government agencies. At a minimum, OMB might want to raise these issues with the National Academy of Sciences at the time that NAS reviews the Bulletin.

Feedback

It may be prudent to request that each government agency report back on some fixed schedule (for example, annually) to OMB on problems encountered with implementing the Bulletin and on suggestions for how the process can be improved and made as efficient as possible. Such reports should be publicly accessible. OMB should also request documentation from agencies concerning stakeholder feedback to them, as this would flag stakeholder concerns and enable an aggregate assessment of how stakeholders are impacted by the implementation of the Bulletin.

Applicability

It is not clear what impact the Bulletin will have on the totality of risk-based standards, determinations, findings, regulations, and agency guidance that are in effect once the Bulletin becomes applicable. This issue needs to be clarified.

All information that is presently disseminated by government agencies and is still in use can be subject to correction requests under the Information Quality Guidelines. With regard to OMB's Bulletin, however, it is not clear how this correction procedure applies to underpinning risk assessments that support standards, determinations, findings, regulations, and agency guidance in instances where the risk assessments are non-conforming (with the Bulletin), for example, because they were conducted prior to when the Bulletin comes into effect.

In other words, for example, if standards presently in effect were developed based on past, non-conforming risk assessments, can such existing standards be exposed to a need for reconsideration based on the argument that the standard is itself based on a risk assessment that does not conform with the Bulletin?

After all, the risk assessment upon which the standard is based is in fact an integral part of the existing, disseminated standard. Analogous to the allowed possibility for requesting correction of existing disseminated data under the Information Quality Guidelines, the existing risk assessment, even if developed prior to implementation of the OMB Bulletin, is disseminated and therefore subject to a correction request. If such a correction to a risk assessment is granted and this leads to a radically different conclusion

about risk, this in turn would negate the credibility of the risk-based standard. Clarification of this matter would be appreciated.

Remarks concerning the formal language portion of the OMB Bulletin

§I. Definitions

Language should be added to Section I to clearly identify the "Information Quality Act" as meaning §515 of Public Law 106-544 (pub. L. No 106-544, 515, 114 Stat. 2763, 2763A-153-154 (2000).

For clarity, language should be added to §I.2 of the OMB Bulletin specifying that "influential" should be interpreted consistent with OMB and agency IQA guidelines. OMB should also clarify how "influential" risk assessments are to be identified. Given the demonstrated impacts of such information[2] this should include IRIS-type assessments.

§II. Applicability

Language stating that the Bulletin does not apply to:

> *an individual product label, or a risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use*

appears to exempt FDA's drug risk assessments. If this perception is correct, why should expectations laid out in the Bulletin for risk assessments be exempted in this instance?

§III. Goals

Objectives to be accomplished in support of achieving goals must be clearly stated, easily understood, and incorporate performance metrics that are measurable and demonstrate compliance with the Bulletin standards. To strengthen this expectation, language should be added to §III.2 directing agencies to the OMB IQA guidelines, the OMB peer review guidelines, and OMB Circular A–4 in deciding on scope, content and acquisition of additional information.

§IV. General risk assessment and reporting standards

To emphasize the point, language should be added to the introduction of §IV, clearly stating that risk assessments disseminated by federal agencies are subject to both OMB's IQA Guidelines and the agency's IQA Guidelines.

[2] See U.S. Chamber of Commerce, Request for Correction of Data in Databases and Models Disseminated by EPA (RFC 04019), May 26, 2004 and U.S. Chamber of Commerce, Request for Reconsideration of RFC 04019 (RFR 04019A) at http://www.epa.gov/quality/informationguidelines/iqg-list.html.

In §IV.2(b), following the passage:

….*the hazard of concern"*

add:

and consideration of evidence regarding the causative role of all potential factors in producing the disease of interest

as disease causation is multi-factorial in nature.

§IV.3 directs agencies to provide a characterization of risk, qualitatively and, *whenever*[3] possible, quantitatively, and that when a quantitative characterization of risk is provided, a range of plausible risk estimates shall be provided. The Bulletin could be strengthened by indicating that the range of plausible risk estimates should include an estimated level of confidence associated with each estimate.

§IV.4(a) advises:

Be scientifically objective: as a matter of substance, neither minimizing nor exaggerating the nature and magnitude of risks.

But how is this to be achieved? This point lends strength to the notion that agencies must present both upper confidence limits of risk estimates, as well as central and lower bound estimates.

In §IV.4(c), include specific reference to the SDWA standards to insure that they are implemented and followed. In §IV.5, as there is no obvious reason not to, the phrase:

… *whenever possible* …

should be removed and replaced with:

... *the agency shall* …

Moreover, this section should require a discussion of how alternative assumptions affect conclusions about the strength of the validity of any particular assessment. Similarly, use of "*whenever possible*" should be struck from §IV.6(c) and §IV.7(e). The requirements indicated in

[3] However, albeit characterized by varying degrees of reliability, it should always be possible to provide quantitative expressions of risk along with expected confidence estimates. Providing such information could improve the utility of information used by decisionmakers.

§IV.7(c) – §IV.7(e) should be a requisite of all risk assessments not just those in support of rulemakings.

§V. Special standards for influential risk assessments

In §V.1, it should be clearly stated that if influential risk assessments are not capable of substantial reproduction by third parties, such risk assessments should be considered unreliable.

§V.2, which directs agencies to compare the results of a risk assessment to other results published on the same topic from qualified scientific organizations, must be clarified. Does "published" include non-peer reviewed reports, such as government reports or company-internal risk assessments? Moreover, per the discussions included in these comments, what constitutes a "qualified scientific organization"? Absent clarification, discretion as to what is a qualified scientific organization will fall to the various agencies, and, lacking some common framework, the public will be left to its own determinations as to what is a qualified organization. This serves no one well.

In §V.3 the text:

Highlight central estimates …

could be improved if it read:

Present central estimates …

as this modification clearly communicates that a full range of risk estimates "shall be" provided.

In the Bulletin preamble, OMB indicates that when qualified specialists disagree as to the adversity of an endpoint, the extent of difference of scientific opinion should be disclosed. This observation should be explicitly stated (with reference to both environmental and ecological risks) in the formal text of §V.7, along with (to improve transparency) encouragement to employ graphical portrayals of different safe levels based on different effects observed in various experiments. The basis upon which "adversity" is established should be clearly articulated and scientifically defensible. The text in §V.9

Consider all significant comments received …

could be strengthened by revising it to read

Agencies shall consider all significant comments received …

and similarly, the word "shall" should precede the text of §V.9(a) and §V.9(b).

§VI. Updates

Notwithstanding resources to act, agencies should be required (without any predisposition as to the direction of a possible revision) to update "influential" risk assessments whenever relevant and scientifically plausible information becomes available. Given the importance of such assessments, necessary resource contingencies for performing updates should be established.

§VII. Certification

Refer to the general discussion included above in these comments.

§VIII. Deferral and waiver

Refer to the general discussion included above in these comments.

§IX. OIRA and OSTP responsibilities

No additional remarks are provided in these comments.

§X. Effective date

No additional remarks are provided in these comments.

§XI. Judicial review

No additional remarks are provided in these comments.